Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Colourstart Test 65mcg Cutaneous Patch (paraphenylenediamine; PPD)

Public Consultation

Proposal to make available from general sales outlets without prescription

The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK government agency responsible for regulating medicines and medical devices. We continually review the safety of medicines and vaccines in the UK and inform healthcare professionals and the public of the latest updates through several means, including public reclassification reports. Suspected side-effects to any drug or vaccine can be reported to MHRA by both healthcare professionals and members of the public via the Yellow Card Scheme (http://www.mhra.gov.uk/yellowcard)

Ref: ARM 97

Colourstart Test 65mcg Cutaneous Patch (paraphenylenediamine; PPD)

Proposal to make available from general sales outlets without prescription

We want to know what you think

- Colourstart Test 65mcg Cutaneous Patch is a ready-to-use patch test used to screen for allergy to an ingredient paraphenylenediamine (also known as PPD or `para') which is the commonest and most well-known component of hair colourants.
- PPD is known to cause allergic reactions which may be severe, in some individuals.
- Colourstart Test 65mcg Cutaneous Patch is used prior to applying hair colourant. If reaction to the patch test is positive, hair colourant should not be used.
- Colourstart Test 65mcg Cutaneous Patch is currently licensed as a prescription only medicine.
- We propose to make it available in general sales outlets, such as supermarkets and hair dressing salons, without prescription.
- The Commission on Human Medicines has advised that this product can be available as a General Sale List (GSL) medicine.
- We want to know what you think about this change.

Please tell us your views – please use the form at the end of this document.

The deadline for comments is **7 November 2018**.

In this document there is:

- A summary of the proposed change and the background
- A copy of the patient information leaflet and label proposed if the change goes ahead
- A form for your response

The full name of the medicine is `Colourstart Test 65mcg Cutaneous Patch' – in this document, we will call it 'Colourstart Test Patch.'

Contents:

Product details:

Product name: Colourstart Test 65mcg Cutaneous Patch

Active substances: paraphenylenediamine (PPD)

Licence holder: Trichocare Diagnostics Limited

Route of sale/supply: Current - on prescription (POM); Proposed – General Sale List (GSL)

Indication: A screening test for potential allergic contact dermatitis to PPD in people aged 16 years of age and over.

Marketing Authorisation Number: PL 33784/0001

Consultation is open from: 17 October 2018 – 7 November 2018

Reference: ARM 97

Contact: reclassification@mhra.gov.uk

1. Background on deciding where medicines are available

The role of MHRA
MHRA regulates medicines and medical devices in the UK, on behalf of the UK Licensing Authority. This means that MHRA decides whether medicines are available:

- on prescription only - 'prescription only medicine' (POM)
- bought from pharmacies - 'pharmacy medicine' (P)
- bought from other shops - 'general sales list medicine' (GSL)

What is re-classification of a medicine?
Making a change on where a medicine is available is called 'reclassification'. This is sometimes referred to as 'switching'. To decide on this change, MHRA may:

- take advice from its committees of external experts
- take advice from a group ('stakeholder group') of health professionals and representatives of people affected by the classification change
- run a public consultation

When a medicine is reclassified, it is usual for reclassification from POM to P to occur in the first instance, and once some experience is gained with the product in the pharmacy (P) setting, further reclassification from P to GSL may occur. In some cases, a medicine may be reclassified directly from POM to GSL, where it meets the necessary requirements and it is safe to do so. To be reclassified directly from POM to GSL, a medicine must meet both the requirements of POM to P and P to GSL reclassification.

To be reclassified from POM to P a medicine must:

- be unlikely to be a direct or indirect danger to human health when used without the supervision of a doctor, even if used correctly
- be generally used correctly (ie not frequently or to a wide extent used incorrectly)
- not contain substances or preparations of substances where the activity of the product or its side effects require further investigation
- not normally be prescribed by a doctor for injection (parenteral administration)

To be reclassified from P to GSL, it must be demonstrated that the medicine may be supplied with reasonable safety in outlets other than in pharmacies. `Reasonable safety' is defined as `Where the hazard to health, risk of misuse and need for special precautions in handling of the medicine are small, and where the wider sale would be a convenience to the purchaser'.

What evidence is needed?
A company or organisation can ask MHRA for a medicine to be available as a pharmacy medicine or a general sale medicine. To do this, they need to get together evidence to show that the medicine

a) is likely to be used appropriately, and
b) with relatively little danger to the public.

This evidence needs to focus on the risk to the public. This includes evidence on the possible abuse or misuse of the medicine. The evidence may include:

- clinical studies
- evidence showing acceptable level of side effects
- advice of experts
- views of relevant health professionals and their professional bodies
- views of relevant public associations and individuals with an interest in the medicine under consideration. #

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Who makes the final decision?

The final decision on whether to approve a change is made by the MHRA, on behalf of the UK Licensing Authority.

2. About Colourstart Test Patch

Colourstart Test Patch is used to screen for potential allergic contact dermatitis (a reaction on the skin, usually seen as an itchy rash, redness and tiny blisters, resulting from contact with a substance to which you are allergic) to paraphenylenediamine (PPD) in people aged 16 years of age and over, prior to applying hair colourant. This medicine was licensed as a Prescription Only Medicine (POM) in 2012 and is not currently marketed.

PPD is the commonest and most widely-known component of hair colourants. It has a strong capacity to produce allergic reactions when in contact with the skin and these reactions may be severe, in some people.

The Allergy Alert test (AAT) or so called `open test' is recommended by hair colourant manufacturers to test for potential allergy to a product before use. With this test, a small amount of hair colourant, which contains PPD + other chemicals, is applied behind the ear and left for 48 hours to detect potential allergy to the product. Exposure to PPD with this method is variable depending on the product and amount applied behind the ear.

Colourstart Test Patch is a test for potential allergy to PPD only. In contrast to the AAT, it provides a controlled and defined exposure to PPD. Colourstart Test Patch may be used instead of the AAT to detect potential allergy to PPD. If there is a positive reaction to the test patch, hair colourant should not be used.

The Commission on Human Medicines (CHM) has advised that this product can be made available as a General Sale List medicine. This report outlines the background to this decision. Please tell us your views by using the response form at the end of this document (Annex 1). The deadline for comments is **7 November 2018**.

The patient information leaflet, label and summary of product characteristics are provided in Annex 2, 3 and 4.

What is in Colourstart Test Patch?

Colourstart Test Patch is a self-adhesive plaster consisting of two patches, one containing 65 micrograms of PPD (active patch) and the other patch with no PPD (control patch).

There is currently one other licensed medicinal product, containing PDD as an active ingredient. This product has a test strip consisting of a series of 12 different allergen patches, one of which contains 65 micrograms of PPD and is licensed as a prescription only medicine for diagnostic use in investigating patients with a history of dermatitis and a suspicion of having contact allergy and/or allergic contact dermatitis.
Colorstart Test Patch would be the first medicine containing PPD to be available without prescription.

What is Colourstart Test Patch used for?

Colourstart Test Patch is a medicine used as a screening test for potential allergic contact dermatitis to paraphenylenediamine (PPD) in people aged 16 years of age and over. It is recommended for use before applying hair colourant.

3. Proposal to make Colourstart Test Patch available as a General Sale List medicine

Who has made the proposal?
The licence-holder for Colourstart Test Patch (Trichocare Diagnostics Limited) has applied to make this product available through general sales outlets.

What is the view of the Commission on Human Medicines?
The Commission on Human Medicines has advised that Colourstart Test Patch can be available as a General Sale List medicine. Views on the use of this medicine as a screening test for potential allergy to PPD in people aged 16 years of age and older were also sought at a meeting of the Gastroenterology, Rheumatology, Immunology and Dermatology Expert Advisory Group (GRID EAG). The views of the GRID EAG were summarised and provided for CHM when they considered the reclassification application.

Proposed terms of reclassification
What are the details of this change?
The application proposes to make Colourstart Test Patch available through general sales outlets for:

- topical use (application to the skin)
- as a screening test for potential allergic contact dermatitis to paraphenylenediamine (PPD) in adults and adolescents aged 16 years of age and over
- single use only, consisting of surgical tape with two polyester patches (one active patch containing 65mcg of PPD + one negative (control) patch with no PPD)

4. How was the proposal assessed for Colourstart Test Patch being available as a General Sale List medicine?

The proposal for Colourstart Test Patch is for reclassification from POM to GSL.To be reclassified from POM to GSL, a medicine must meet both the requirements of POM to P and P to GSL reclassification. Therefore, this product was assessed firstly against the criteria for a medicine to be classified as P and then against the criterion for a medicine to be classified as GSL.

For a medicine will to be classified as P it must **not** meet any of the criteria for POM classification, which are set out in the Human Medicines Regulations 2012, regulation 62(3).

These criteria are as follows:

Prescription only (POM) status will apply where:

1. A direct or indirect danger exists to human health, even when used correctly, if used without medical supervision
2. There is frequently incorrect use which could lead to direct or indirect danger to human health
3. Further investigation of activity and/or side effects is required
4. The product is normally prescribed for parenteral administration (by injection)

In addition, for a medicine to be classified as GSL it must also be demonstrated that it **does** meet the GSL criterion, which is set out in the Human Medicines regulations 2012, regulation 62(5). This criterion is as follows:

`GSL may be appropriate for medicines which can, with reasonable safety, be sold or supplied otherwise by or under supervision of a pharmacist.'

`Reasonable safety' is defined as `where the hazard to health and risk of misuse and need for special precautions in handling are small, and wider sale would be a convenience to the purchaser.'

Assessment of suitability for Pharmacy availability

The MHRA assessed the application against the criteria stated above.
The key aspects of the assessment of reclassification are summarised below.

Criterion 1 - `It is likely to present a direct or indirect danger to human health, even when used correctly, if used without medical supervision.

The main criterion that needed to be considered in the reclassification of Colourstart Test Patch to P was that it does not present a direct danger to human health if used, even correctly, without supervision of a doctor. A direct danger may be present if the product causes adverse reactions that are important because of their seriousness, severity, or frequency. A danger may also be present if the reaction is one for which there is no suitable preventative action such as being able to identify the group of patients who are at risk if they use the product without medical supervision so that they may be excluded from using the product. Direct danger may also arise from drug interactions with commonly used medicines. For the product to be used without prescription, the drug interactions would need to be preventable.

Direct danger to human health

The purpose of using an allergy screening product such as Colourstart Test Patch is to determine whether a person is sensitive to PPD by using a small controlled amount of PPD, rather than using an uncontrolled amount, for example with the Allergy Alert Test (AAT), or using nothing at all.

The amount of PPD in Colourstart Test Patch (65 microgram) is very much lower than found in hair colourants which may be up to 2% (the maximum permitted for hair colourants in line with EU Directive 2009/130/EC). As an example, a total quantity of 50mL of hair colourant mixed and ready to use may contain up to 1g of PPD.

Colourstart Test Patch has not to date been marketed. Safety of the product is based on that of a reference product (with test strip consisting of a series of 12 different allergen patches, one of which contains 65 micrograms of PPD) and a clinical study. The main adverse events for the product are irritation caused by the surgical tape adhesive and local itching where the patch is applied. These effects are usually mild and disappear in one to two days. In the case of an individual who is sensitive to PPD, a positive reaction on the skin under the active patch (containing PPD) will occur. This will be usually show as a rash, redness and tiny blisters. The skin under the patch may also itch and feel warm. This reaction to the product is as would be expected in individuals who are sensitive to PPD and therefore, should not use hair colourant. A positive reaction usually disappears within 1 to 2 weeks, but on occasion may persist for weeks or months and may leave a temporary area of pale-coloured or darker coloured skin. A test reaction which appears more than 10 days after application of the patch may be a sign of contact sensitisation (allergy the ingredients in the patch, including PPD), which may occur with patch testing.

Individuals who experience a positive test reaction should not use hair colorant and are advised to seek medical advice. In the case of a severe patch test reaction, for example,

redness of the skin with large fluid filled blisters, the individual should seek medical advice immediately.

Direct danger with Colourstart Test Patch may potentially arise in the following situations:

- with incorrect reading of the patch test result
- when used by individuals taking certain medicines
- when used by individuals for whom the product is contraindicated (should not be used)

The main direct danger of using Colourstart Test Patch without medical supervision is that of incorrect reading of the test patch result, leading to use of hair colourant when sensitive to PPD and, as a consequence, experiencing an allergic reaction.

As part of the application to reclassify this product from POM to GSL and on the recommendation of the Commission on Human Medicines (CHM), the applicant has provided results of a clinical study comparing Colourstart Test Patch with the Finn Chamber (a skin patch test chamber used for patch testing) in detection of PPD allergy in subjects with known or suspected allergy and those with no known allergy to PPD. There were recruitment difficulties with this study, in part possibly due to increased media attention alerting potential participants to the risk of severe allergic reaction to ingredients in hair colourants.

However, the study demonstrated that participants were able to identify allergy, if present, and in general took a more conservative approach to interpreting the patch test result than the study investigators. Adverse events were mainly mild in nature and, in most cases, resolved without treatment.

The applicant also provided details of a Patient Group Direction (PGD) which was undertaken with Colourstart Test Patch. A PGD is a written protocol by which a pharmacist can provide prescription only medicines to the public without the need of a prescription from a doctor. The PGD carried out was a means of allowing easier access to Colourstart Test Patch while ensuring that a pharmacist would be involved with the supply and advising on the use of the medicine in each individual participant. The PGD was not completed as planned and, as with the clinical study, there were recruitment difficulties. However, the PGD did not raise any safety concerns with Colourstart Test Patch.

Incorrect interpretation of the patch test result may occur if an individual is taking medicines such as corticosteroids or immunosuppressants. These medicines may supress a positive test reaction, resulting in a false negative test result. Colourstart Test Patch is contraindicated, and therefore should not be used, by individuals taking such medicines. The patient information leaflet states `Do not use Colourstart if you are taking oral or topical steroids (such as prednisolone, betamethasone, fluticasone, hydrocortisone) or immunosuppressant medicines (such as tacrolimus, cyclosporine, mycophenolate, azathioprine, sirolimus), as they may supress a positive reaction.' Similarly, the outer carton label states not to use Colourstart `if you are taking steroid medicines, using steroid ointment/creams, or taking immunosuppressant medicines'.

Colourstart Test Patch is contraindicated and therefore should not be used in the following situations:

- in individuals with a history of a reaction to black henna tattoo or presence of a current black henna tattoo (This is because there may be cross-sensitivity to PPD and black henna tattoo)
- pregnant or breast-feeding women
- individuals with acute dermatitis (This is because flare up of dermatitis may occur)
- use of the allergy alert test (AAT) at the same time as/in addition to Colourstart Test Patch (This is because there is potential for sensitisation to PPD with repeated exposure over time)

Repeated use leading to sensitisation to PPD, may potentially occur with use of Colourstart Test Patch. This may also occur for example with repeated use of the Allergy Alert Test (AAT) method and with the use of hair colourants themselves. With Colourstart Test Patch an individual is exposed to a small controlled amount of PPD.

The applicant has provided references from the literature and report written by a consultant toxicologist which confirms that risk of sensitisation with use of Colourstart Test Patch is low. Nonetheless, to minimise this potential risk, individuals should not perform the AAT at the same time as/or in addition to using Colourstart Test Patch. The patient leaflet for the product includes information regarding sensitisation to PPD, a warning not to perform the AAT in addition to using Colourstart Test Patch and advice to the individual to consult their doctor if sensitisation does occur.

Use of Colourstart Test Patch without medical (or other healthcare professional) supervision is unlikely to result in direct danger. The product is supported by appropriate information for the user (patient information leaflet and labelling) to minimise risks associated with use in the absence of healthcare professional supervision. The patient information leaflet gives clear directions to the user on how to apply the patch and interpret the patch test result.

The MHRA considers that the direct risks associated with Colourstart Test Patch can be minimised to an acceptable level to be used without medical supervision.

Indirect danger to human health

Medicines may present an indirect danger when symptoms to be treated are caused by a range of different conditions. If the patient cannot easily self-diagnose the cause of such symptoms, it may be inappropriate to provide a product to treat symptoms without treating the underlying disease.

An important example of an indirect danger is when treating symptoms might mask an underlying condition requiring medical attention. Use of the medicine might delay diagnosis and definitive treatment and jeopardise the chance of more successful therapy. Consideration should be given to whether an indirect danger might exist and if so, whether the risk, its frequency and seriousness of the consequences would make reclassification unacceptable. Additional warnings such as a recommendation to seek medical advice if symptoms continue beyond a stated time period, may be necessary in such instances.

Individuals purchasing and intending to use Colourstart Test Patch will be aware of the risks associated with use of hair colorants. In using Colourstart Test Patch, individuals will be screening for potential allergy to the ingredient PPD. If they react positively to the patch test, they are instructed not apply hair colourant, therefore preventing a potentially serious allergic reaction.

The MHRA considers that the indirect risk associated with use of Colourstart Test Patch is low.

Criterion 2 - `It is frequently and to a very wide extent used incorrectly, and as a result is likely to present a direct or indirect danger to human health.

Addiction, dependence, recreational use, and misuse are considered as incorrect use in relation to this criterion.

Colourstart Test Patch has not been marketed as a prescription product. Data is available for the reference product (see section 2, page 5 & section 4, page 7) and from a clinical study performed with Colourstart Test Patch. From data available, there is no evidence to suggest that Colourstart Test Patch will be frequently and to a very wide extent used incorrectly. PPD is not considered to be a compound associated with abuse or addiction potential and there is no known illicit use of the compound.
Incorrect use of Colourstart Test Patch, frequently and to a very wide extent would therefore not be expected, nor would abuse of the product.

Criterion 3 - `It contains substances or preparations of substances of which the activity requires, or the side effects require, further investigation.'

PPD is the commonest and most widely-known component of hair colourants which has a strong capacity to produce allergic reactions when in contact with the skin. The purpose of using Colourstart Test Patch is to screen for potential allergy to this compound prior to using hair colourant.

There is limited experience of PPD as an ingredient in a medicinal product. From the clinical study conducted, no major safety issues were identified. The most common adverse events were irritation caused by the surgical tape adhesive and local itching where the patch is applied, and these were likely to resolve spontaneously after removal of the patch. Sensitisation to PPD may occur with patch testing. This may also occur with use of the AAT method to detect potential allergy to hair colorant products and with use of hair colourants themselves.

Criterion 4 - `It is normally prescribed by a doctor for parenteral administration (by injection).'

Colourstart Test Patch is for application to the skin only, so this criterion does not apply.

<u>Assessment of suitability for availability in general sales outlets</u>

A GSL medicine may be sold in general sales outlets in the absence of healthcare professional advice. It is important therefore, that a GSL medicine may be safely sold or supplied without need of a consultation with a doctor or pharmacist.

Hazard to health

This is addressed under POM criterion 1 (page 7)

Risk of misuse

This is addressed under POM criterion 2 (page 9)

Special precautions in handling

There are no special handling requirements for Colourstart Test Patch that would prevent its availability as a GSL medicine.

Role of the pharmacist

Individuals purchasing and intending to use Colourstart Test Patch will be aware of the risks associated with the use of hair colourants and the need to test for potential allergy to hair

colourants prior to use. Advice of a pharmacist is not considered necessary for the consumer to purchase Colourstart Test Patch for its intended use.

Convenience to the purchaser

Availability of Colourstart Test Patch in hair dressing salons or other outlets where hair colourants are sold is considered appropriate. Most hair colourants are purchased outside pharmacies and the ATT test is undertaken without advice from a pharmacist. Limiting Colourstart Test Patch to pharmacy (P) legal status would unnecessarily limit the availability of the test.

5. Further details on the application

Risk Management Plan
The application contains a risk management plan (RMP) which was required when the product was first authorised. The RMP documents the following:

- the known safety profile of the medicine, including any important identified and potential risks
- what is not known about the safety profile (`missing information')
- how the safety profile will be monitored after the medicine is licensed, including any plans for further studies to actively gain more knowledge about the safety of the medicine (`additional pharmacovigilance activities')
- how any important risks will be prevented or minimised in patients (`risk minimisation measures') and how the usefullness and effectiveness of the risk minimisation measures will be assessed

The RMP for Colourstart Test Patch has identified the main risks associated with the product and proposes how these will be managed through routine pharmacovigilance (monitoring and reporting of adverse events for a medicine, for which there are no special safety concerns) and via the product information (SmPC, labelling and patient information leaflet). No additional risk minimisation measures are proposed for the product.

Label and leaflet
The patient information leaflet and label are provided in Annex 2 and 3.

Summary of Product Characteristics
The Summary of Product Characteristics is provided in Annex 4. This document is a description of the properties of Colourstart Test Patch and the conditions attached to its use. It is used as a reference by healthcare professionals.

6. What do you think?

- Colourstart Test 65mcg Cutaneous Patch is a ready-to-use patch test used to screen for allergy to an ingredient paraphenylenediamine (also known as PPD or `para') which is the commonest and most well-known component of hair colourants.
- PPD is known to cause allergic reactions which may be severe, in some individuals.
- Colourstart Test 65mcg Cutaneous Patch is used before applying hair colourant. If reaction to the patch test is positive, hair colourant should not be used.
- Colourstart Test 65mcg Cutaneous Patch is currently licensed as a prescription only medicine.

- We propose to make it available in general sales outlets, such as supermarkets and hair dressing salons, without prescription.
- The Commission on Human Medicines has advised that this product can be available as a General Sale List (GSL) medicine.
- We want to know what you think about this change.

Please tell us your views using the form on the next page in Annex 1. The deadline for comments is 7 November 2018.

ANNEX 1

Response document for MHRA public consultation on the proposal to make Colourstart Test Patch available from general sales outlets without prescription

Ref: ARM 97

Your details
Name:

Position (if applicable):

Organisation (if applicable):

Email:

1. Do you consider that Colourstart Test Patch should be available as a General Sale List (GSL) medicine?

Yes ☐ No ☐ Not sure ☐

Please provide any comments or evidence to support your response:

2. Do you have any specific comments on the leaflet or the label provided in the public reclassification report for Colourstart Test Patch?

3. Do you have any other comments on the reclassification?

4. The MHRA may publish consultation responses. Do you want your response to remain confidential?

Yes ☐ Partially* ☐ No ☐

*If partially, please indicate which parts you wish to remain confidential. In line with the Freedom of Information Act 2000, if we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. Responses to consultation will not normally be released under FOI until the regulatory process is complete.

Responses can be continued onto a separate page if required. This form should be returned by email (reclassification@mhra.gov.uk) to arrive by **7 November 2018.** Contributions received after that date cannot be included in the exercise.

Colourstart® Test 65 mcg Cutaneous Patch

p-Phenylenediamine (PPD) 80 micrograms/cm^2
(65 micrograms/patch)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Colourstart is available without a prescription. However, you still need to use it carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Colourstart is and what it is used for

Colourstart is a ready-to-use patch test for finding out if you might be allergic to an ingredient (PPD) in hair colorants. PPD, along with other chemicals, is present in many hair colorants. PPD is known to cause allergic reactions, which may be severe, in some individuals.

If a substance to which you are allergic (an allergen) comes into contact with your skin it causes a reaction often called contact dermatitis.

The test consists of surgical tape with two patches. One of the patches (marked A+) is the active patch containing PPD. The other patch (marked A-) is the control patch with no PPD present.

Colourstart works by showing if you are allergic to the PPD patch (marked A+). If you are likely to be allergic to PPD then the skin under the patch (marked A+) will react to it becoming red and inflamed and may have tiny blisters. If you have not shown an allergic response, the skin under this patch will not react. It will look normal and similar to the skin under the control patch (marked A-).

If your hair colorant recommends that you carry out an allergy alert test prior to application, Colourstart can be used instead of this test to test for allergy to PPD.

The absence of a reaction following use of Colourstart does not guarantee a safe hair colour treatment, but by using this product correctly, you can minimise the risk of reaction to hair colorant.

2. What you need to know before you use Colourstart

Do not use Colourstart if you

- suspect or know that you are allergic to PPD or any of the other ingredients of this medicine (See section 6).
- if you have active dermatitis on your skin (e.g. redness, swelling, itching)
- have previously experienced an allergy to hair colorant
- if you are pregnant or breast-feeding
- if you are taking oral or topical steroids and other immunosuppressant medicines

See section “Taking other medicines and Colourstart” below.

A temporary black henna tattoo may increase your risk of having an allergic reaction when you colour your hair.

DO NOT use Colourstart if you have a temporary black henna tattoo

DO NOT use Colourstart if you have had any reaction to a temporary black henna tattoo in the past.

DO NOT perform the “Allergy Alert Test” as instructed on hair colorants in addition to using this medicine.

Colourstart is not recommended for adolescents and children under 16 years of age. Hair colorants are not intended for use by children under 16 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before using Colourstart if any of these factors apply to you. Your doctor or pharmacist will be able to decide what to do.

Take special care with Colourstart

- if you go out in the sun regularly, as you should avoid exposing the area where the patch is applied to the sun. This is particularly important during the summer.
- avoid getting the patch excessively wet as this may cause the patch to loosen and stop working properly. Take care therefore when bathing, showering or during periods of exercise where you may sweat.
- in rare instances you may become allergic to PPD present on the patch. Any reaction which occurs at the site of where the patch was applied, approximately 10 days later, may be a sign of contact sensitisation. If this happens talk to your doctor or pharmacist and **DO NOT** use hair colorants if this happens.

Taking other medicines and Colourstart

Do not use Colourstart if you are taking oral or topical steroids (such as prednisolone, betamethasone, fluticasone, hydrocortisone or immunosuppressant medicines (such as tacrolimus, cyclosporine, mycophenolate, azathioprine, sirolimus) as they may suppress a positive reaction.

Pregnancy, breast-feeding and fertility

Pregnant women should not use Colourstart.

If you are pregnant or think you might be pregnant or are planning to have a baby ask your doctor or pharmacist for advice before taking this medicine.

You should not use Colourstart if you are breast-feeding your baby.

Other warnings

DO NOT perform the “Allergy Alert Test” as instructed on hair colorants in addition to using this medicine.

Driving and using machines

There are no known effects of Colourstart on driving or using machinery.

colourstart®

Continued overleaf

3. How to use Colourstart

Always apply the self-adhesive patch at least 48 hours (2 days) or ideally 5 days before any colouring process.

Always use this medicine exactly as described in this leaflet.

Colourstart is not recommened for adolescents and children under 16 years of age.

Adults and adolescents aged 16 years and over:

The instructions and diagrams below relate to the use of the patch on the upper arm.

Select a clean, dry, intact area of skin to apply the patch. The patch should be applied only to healthy skin that is free of acne, scars, dermatitis or any other condition that may interfere with the test results. Avoid placing the patch on areas of the skin where creams or emollients have been applied as these may affect how the patch sticks to the skin.

Directions

1. Wash your hands before applying the patch.
2. Peel open the foil pouch and remove the patch.

   Remove the tab marked "1" from the surface of the patch whilst taking care not to touch the patches (see Figure 1).

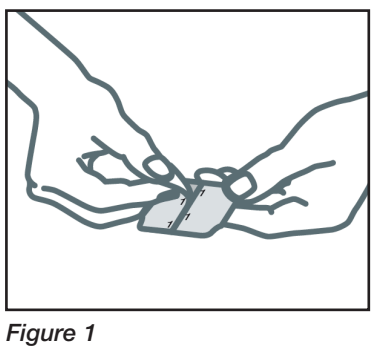

Figure 1

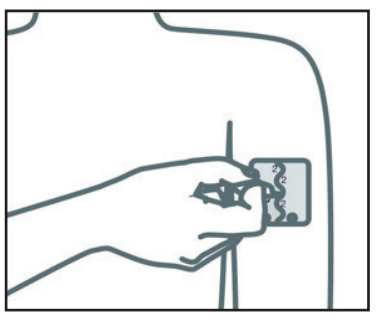

Figure 2

3. Whilst holding the patch at the edge with finger tips place it on the upper arm (above the elbow but below the shoulder) where you will be able to see the test results.

   The patch should be smoothed from the centre to the outer edges (see Figure 2).

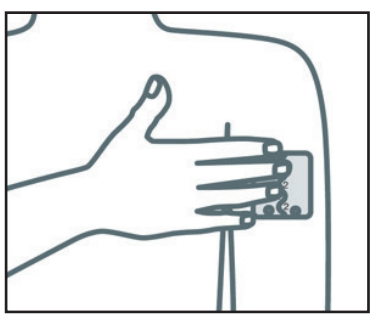

Figure 3

   The second tab, marked with a "2" should then be removed (see Figure 3) and the patch smoothed from the centre to the outer edges (see Figure 2).

   Once the patch is in place you will see one patch marked "A+", which is the active patch containing PPD and one clear patch marked "A-", which is the control patch with no PPD allergen.

You should wear the patch for at least 48 hours without removing it.

If you experience any symptoms of discomfort or there is a noticeable difference in how your skin looks or feels in this 48 hour period, remove the patch and wash the area gently with water as it may be a positive result. **DO NOT** apply hair colorant.

Talk to your pharmacist or doctor if you are at all unsure.

After 48 hours you may remove the patch.

Identifying the results

Wait 20 to 30 minutes after removing the patch and then examine your arm to look for any signs of an allergic "positive" test reaction. If the test is positive, indicating potential allergy to hair colorant, the area under the patch marked A+ will look different to that marked A-.

A positive result is usually seen as a rash, redness and tiny blisters. It may also itch and or feel warm. Note that the redness may not be evenly spread across the area.

If you see a reaction to Colourstart, **DO NOT** apply hair colorant.

You may suffer a worse reaction. You should seek medical advice from your doctor.

If a severe patch test reaction develops which is seen as redness with large fluid filled blisters, talk to your doctor immediately. DO NOT apply hair colorant.

If no positive test result is seen continue to look at the area for a further 48 to 72 hours to see if there is a change in the skin. There should be no visible differences in the two patches marked A+ and A-.

PPD sensitivity sometimes causes reactions which may not appear until 4 to 5 days after the application. If this occurs seek advice from your doctor.

The absence of a reaction following use of Colourstart does not guarantee a safe hair colour treatment, but by following these safety instructions, you can minimise risk.

If you use more Colourstart than you should

This is not possible if you use Colourstart only as directed as it is a single use patch.

If you put on more than one patch, or if anyone else has put a patch on their skin accidentally, remove it as soon as you can and wash the area gently with water.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The side effects could include:

- a flare-up of your dermatitis, if the test is used during an active phase of your skin disease.
- sensitisation to the substance on the test panel. A test reaction that appears later than 10 days after application may be a sign of contact sensitisation. Contact sensitisation occurs when you develop an allergy to a substance due to the use of Colourstart. This may in rare instances occur with patch testing. If this happens talk to your doctor or pharmacist and **DO NOT** use hair colorants.
- a positive test reaction usually disappears within 1-2 weeks. On rare occasions, a positive test reaction may last for weeks or months. Such reactions will leave a temporary area of pale coloured skin or hyperpigmentation (area of darker coloured skin).
- irritation and or itching caused by the surgical tape glue may occur, but usually disappears rapidly.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Colourstart

Keep this medicine out of the sight and reach of children.

Colourstart should be stored below 25°C.

Do not use Colourstart after the expiry date which is stated on the foil pouch. The expiry date refers to the last day of that month.

Do not use this medicine if you notice that the foil pouch is open or damaged.

The used patch should be folded, sticky sides together, put back in the empty pouch and disposed of carefully.

Always dispose of used Colourstart patches sensibly, away from the reach of children and animals.

6. Contents of the pack and other information

What Colourstart contains

- The substance in the 'active' (marked A+) patch is: p-Phenylenediamine ((PPD) 65 micrograms.

The patch marked (A-) is the control, which does not contain PPD

- The other ingredients in the patches are: ethanol, povidine 90

What Colourstart looks like and contents of the pack

Colourstart consists of surgical tape with two patches. One of the patches (marked A+) is the active patch containing PPD. The other patch (marked A-) is the control patch with no PPD.

Colourstart is available as a single use self-adhesive plaster inside a foil pouch.

The foil pouch also contains a special type of paper (desiccant) to keep the patch fresh during storage.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Trichocare Diagnostics Ltd
Berry End Farm House
Bedfordshire MK17 9EB

Manufacturer
Smartpractice Denmark ApS
DK-3400 Hillerod
Denmark

This leaflet was last revised in July 2018.

colourstart®

Colourstart® Test 65 micrograms Cutaneous Patch

Colourstart is a ready-to-use patch test for finding out if you might be allergic to an ingredient (PPD) in hair colorants. PPD, along with other chemicals, is present in many hair colorants. PPD is known to cause allergic reactions, which may be severe, in some individuals.

INSTRUCTIONS FOR USE
Read the enclosed leaflet carefully before use.

For application to the skin on the outer part of the upper arm. For full instructions, see the enclosed leaflet.

Ingredients: Active patch (marked A+) contains 65 micrograms paraphenylenediamine (PPD) equivalent to 80 micrograms/cm^2. Negative patch (marked A-) contains ethanol 99.5% & polyvidone 90. Also contains ethanol 99.5% & polyvidone 90.

DO NOT USE COLOURSTART IF YOU:

- Are allergic to p-phenylenediamine (PPD)
- Are taking steroid medicines, using steroid ointment/creams, or taking other immunosuppressant medicines
- Have active dermatitis on your skin
- Are pregnant or breast-feeding
- Are under 16 years of age
- Have a temporary black henna tattoo
- Have had any reaction to a temporary black henna tattoo in the past

DO NOT perform the "Allergy Alert Test" as instructed on hair colorants in addition to using this medicine.

colourstart®

Colourstart® Test 65 micrograms Cutaneous Patch

p-Phenylenediamine (PPD) 80 micrograms/cm^2

A screening test for potential allergy to PPD, an ingredient in hair colorants

1 Patch Test consisting of Active patch (A+) and Negative patch (A-)

Keep this carton and leaflet to help you understand how to use this product correctly.

<barcode>

trichocare

MA Holder: Trichocare Diagnostics Ltd.
Berry End Farm House, Bedfordshire
MK17 9EB, United Kingdom
PL 33784/0001

KEEP ALL MEDICNES OUT OF THE REACH AND SIGHT OF CHILDREN

Batch No:
Expiry Date:

Do not store above 25°C. Store in the original pack.

If your hair colorant recommends you carry out an allergy alert test prior to using the product; Colourstart can be used in place of this screening test.

If there is a positive test indicating a potential allergy to hair colour the area under the patch marked A+ will look different to the patch marked A-. A positive result is usually seen as a rash, redness and tiny blisters. It may also itch or feel warm. Note that the redness may not be evenly spread across the area. If you see a reaction to Colourstart, **DO NOT** apply hair colorant. You may suffer a worse reaction.

Talk to your, pharmacist or doctor if you are at all unsure.

colourstart

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colourstart®

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colourstart®

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trichocare

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PL 33784/0001

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Talk to your, pharmacist or doctor if you are at all unsure.

Batch No:
Expiry Date:

trichocare®

51-xxxx -00/1

156 mm

colourstart®

Colourstart® Test 65 micrograms Cutaneous Patch

p-Phenylenediamine (PPD) 80 micrograms/cm²

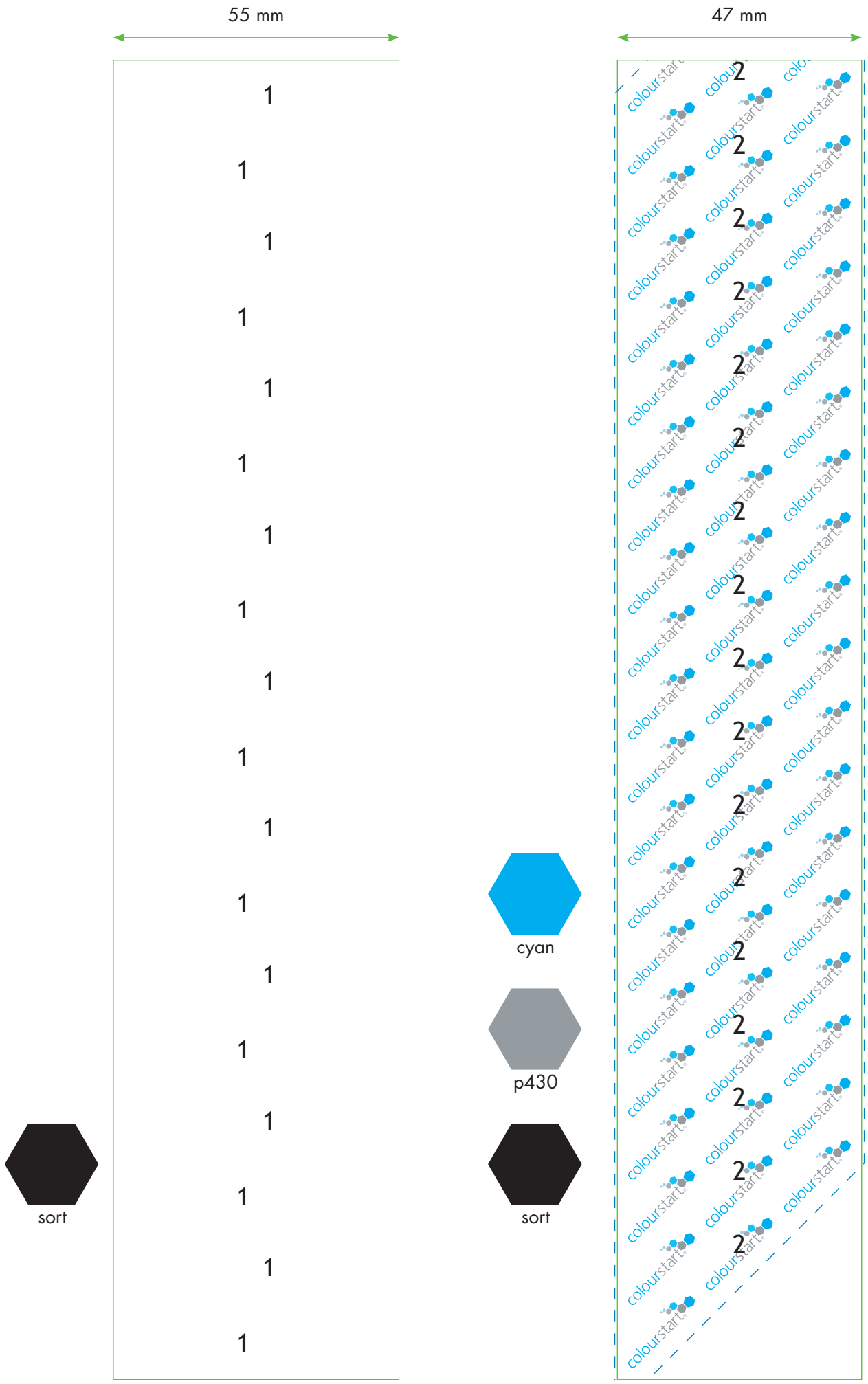
MA Holder: Trichocare Diagnostics Limited, Berry End Farm House, Bedfordshire MK17 9EB

PL 33784/0001

Read the enclosed leaflet carefully before use.

129 mm

OPEN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SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Colourstart Test 65 mcg Cutaneous Patch

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Colourstart is a self-adhesive plaster consisting of a piece of surgical tape with two polyester patches, one with P-Phenylenediamine (PPD) ('active patch') and one control patch ('negative patch').

Active patch (A+)

Each patch contains 65 micrograms PPD in a patch size of 0.9 cm x 0.9 cm (0.81 cm^2), which is equivalent to 80 micrograms/cm^2.

Negative patch (A-)

Each patch contains 0 micrograms PPD in a patch size of 0.9 cm x 0.9 cm (0.81 cm2), which is equivalent to 0 micrograms/cm^2.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Plaster for provocation test (cutaneous patch): self-adhesive plaster for cutaneous use.

For single use only.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Colourstart is a screening test for potential allergic contact dermatitis to PPD in people aged 16 years and over.

4.2 Posology and method of administration

Posology

Adults and adolescents aged 16 years and over:

A dosage level for PPD has been established that is high enough to evoke a reaction even in weakly sensitised patients, yet low enough to minimise the risk of irritant reaction.

Method of administration

The test should be applied to the outer part of the upper arm.

1. Wash your hands before applying the patch.
2. Peel open the package and remove the plaster.
3. Remove the protective tab marked “1” from the surface of the plaster whilst taking care not to touch the patches.
4. Whilst holding the plaster at the edge with fingertips, place it on the outer part of the upper arm (above the elbow but below the shoulder) where the test result will be easily seen. The plaster should be smoothed from the centre to the outer edges.
5. The second set of protective tabs marked “2” should then be removed and the plaster smoothed from the centre to the outer edges.

The test should be applied to healthy skin that is free from acne, scars, dermatitis or any other condition that might interfere with interpretation of results (see section 4.4).

The individual should wear the patch for 48 hours without removing it, being careful not to get the test area wet (water, sweat).

Interpretation

The patch should be removed after 48 hours and the application site inspected 20 to 30 minutes after removal as this allows any irritation resulting from pulling the patch off the skin have resolved. A reading at 48 hours is considered a suitable time point for initial indication of PPD allergy.

It is advisable to continue to monitor the application site for a total of 72 to 96 hours when allergic reactions are fully developed and mild irritant reactions have faded.

PPD, however, sometimes causes reactions which may not appear until 4 to 5 days after the application. Users should be instructed to report this to their doctor.

For the purposes of consumer use a positive test reaction manifests most commonly as papular or vesicular erythema and infiltration at the active area.

Paediatric use

The safety and effectiveness of Colourstart in children has not been established and it should not be used under the age of 16 years.

4.3 Contraindications

Known or suspected allergy to hair dye or PPD or any of the other ingredients of this medicine.

Concomitant use of either topical or oral corticosteroids or any other immunosuppressants, as they may supress a positive test.

Acute dermatitis.

Concomitant use with an allergy alert test.

Previous history of a reaction to black henna tattoo.

The presence of a current temporary black henna tattoo.

Pregnancy or breastfeeding (see section 4.6).

4.4 Special warnings and precautions for use

The patch should be applied only to clean, dry intact healthy skin that is free of acne, scars, dermatitis or any other condition that may interfere with test results. Avoid placing the patch on areas of the skin where creams or emollients have been applied as these may affect how the patch sticks to the skin.

Excessive sweating and sun exposure of the test site is to be avoided.

If a severe test reaction occurs (intense erythema, infiltrate, coalescing vesicles), advice should be sought from a doctor or pharmacist.

Sensitisation to PPD may occur with patch testing. A test reaction that appears on day 10 or later may be a sign of contact sensitisation.

4.5 Interaction with other medicinal products and other forms of interaction

Use of immunosuppressants (including steroids) may suppress a positive patch test reaction (see section 4.3).

4.6 Fertility, pregnancy and lactation

Pregnancy

Reproduction studies have not been conducted with Colourstart. The test is therefore not recommended to be applied to the skin of pregnant women (see section 4.3).

Breastfeeding

No studies have been performed to evaluate absorption of PPD in Colourstart in nursing mothers. Use of Colourstart is therefore not recommended during breast feeding (see section 4.3).

Fertility

There is insufficient evidence available from animal studies in respect to reproductive toxicity.

4.7 Effects on ability to drive and use machines

No known effects.

4.8 Undesirable effects

Local

Irritation caused by the surgical tape adhesive may occur, but usually disappears rapidly.

Local pruritus may occur where the Colourstart patch is applied. This is usually mild and disappears in 1-2 days.

A positive test reaction usually disappears within 1 to 2 weeks. Long-term reactions are positive reactions which persist for weeks or months.

Positive test reactions may leave an area of transient hypopigmentation/ hyperpigmentation at the application site.

General

A flare-up of dermatitis may be observed when testing during an active phase of dermatitis.

Sensitisation (see section 4.4).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Patch testing is a well-established procedure which leads to a delayed hypersensitivity reaction (Type IV) if sensitivity is present.

Although the response can appear as early as six hours, it is believed that the most accurate interpretation may be made between 72 and 96 hours after application since "irritant" reactions will have faded by then.

5.2 Pharmacokinetic properties

There is no information of relevance to the consumer.

5.3 Preclinical safety data

There is no information of relevance to the consumer.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol 99.5%	Solvent
Polyvidone 90	Vehicle

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

18 months.

6.4 Special precautions for storage

Store below 25°C.

The expiry date is stated on the package.

6.5 Nature and contents of container

Each self-adhesive plaster consists of a piece of surgical tape with two polyester patches (A+ active and A- negative), covered by protective sheets of silicone-treated polyethylene marked “1” and “2”and then packed in a sachet of packaging laminate.

The Colourstart sachet also contains a desiccant paper.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Trichocare Diagnostics Ltd,
Berry End Farm House,
Berry End,
Eversholt,
Bedfordshire MK17 9EB,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

PL 33784/0001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 03/12/2012

10 DATE OF REVISION OF THE TEXT

04/2018