

Teva levothyroxine questions and answers

1. Why are Teva levothyroxine 100mcg tablets being withdrawn?

MHRA has received sporadic reports from prescribers and patients, which have increased in Dec 2011 / Jan 2012, raising concerns about the interchangeability of this product with other makes of levothyroxine 100 mcg tablet.

Some patients have experienced a loss of control of thyroid stimulating hormone (TSH) levels when switching between Teva Levothyroxine tablets and other Levothyroxine products. The manufacturer, Teva, has also been experiencing difficulties in manufacturing this product. Results of tests conducted by the MHRA's Medicines Testing Laboratory, suggest that the TEVA product may differ from other products in the amount of levothyroxine that is released over time (dissolution). While it cannot conclusively be said that these issues prove Teva tablets are not interchangeable with other makes of levothyroxine 100 mcg tablets, the MHRA has taken prompt action as a precautionary measure. The MHRA has suspended the manufacture and distribution of Teva tablets having obtained advice from an independent panel of experts, the Commission on Human Medicines (CHM).

Many patients changing to or from the Teva product will not experience any changes in their symptoms. However, there are some patient groups where control of thyroid function is particularly important. These subgroups of patients are:-

Pregnant women, throughout pregnancy but especially in the first 3 months of pregnancy (first trimester)

Those with heart disease

Those under treatment with TSH suppressive doses of levothyroxine following treatment for thyroid cancer

Patients in these groups taking the Teva or Numark Levothyroxine 100 mcg Tablet product should make an early appointment with their doctor.

2. Which levothyroxine products are affected?

Only Levothyroxine 100 mcg tablets that are supplied in the Teva and Numark liveries are affected. The product will bear the Marketing Authorisation number, PL 00289/0039. Levothyroxine products from other manufacturers are unaffected by this suspension

3. Are the TEVA and Numark levothyroxine 100 mcg tablets identical?

Yes, they are identical apart from the packaging.

4. What other makes of levothyroxine 100mcg tablets are available?

A list of manufacturers and suppliers of Levothyroxine 100mcg Tablets is given below:

Product Licence (PL) Number as stated on the label and patient leaflet	Product Name/Brand as stated on the label and patient leaflet	Marketing Authorisation (MA) Holder	Distributed by
PL 00142/0105	THYROXINE TABLETS BP 100 MICROGRAMS	Actavis UK Limited	Almus, or Actavis, or Lloyds
PL 16201/0002	LEVOTHYROXINE 100micrograms Tablets	Forley Generics Limited	Forley Generics Limited
PL 10972/0032	ELTROXIN TABLETS 100MCG	Goldshield Group Limited	Goldshield Group Limited

5. Are all patients that are taking levothyroxine affected?

Patients who are taking tablets of 50 mcg or 25 mcg are not affected. Patients who are taking doses of 100mcg or more, are only affected if they are taking a Teva (or Numark) levothyroxine 100mcg tablet.

6. Why do the Teva 100mcg tablets continue to be available over the next few weeks?

Most patients taking Teva levothyroxine tablets will continue to feel well. Levothyroxine is an essential medicine and it is important that the suspension of the Teva product does not create a shortage with patients being unable to fulfil their prescription. It will take a few weeks before other suppliers have built up stocks of this medicine. .

7. Can I use up my existing Teva 100mcg tablets or should I ask my doctor to change them?

Most patients will not feel any different by continuing with their medication and changing to a different levothyroxine product at their next prescription. Blood test results will then allow any dose adjustment.

8. I have been taking Teva levothyroxine 100mcg tablets for some time. What advice can you give me? Will I be able to obtain further supplies?

Patients who have been taking Teva levothyroxine for some time would be stabilised on this product and feel well. However because of the concerns raised about the interchangeability of this product compared with other levothyroxine tablets, no further supplies of the product will be released for marketing and the tablets will not be available until these issues have been resolved.

Unless you are in the groups of patients described in Q&A no. 1, you should continue to take your Teva tablets and change to a different levothyroxine product at your next prescription. It should not be necessary to make an early appointment with your doctor. Most patients are unlikely to notice any change if they are switched from the Teva product to another Levothyroxine product, however if you start to feel unwell then you should see your doctor.

9. What should I do if I feel unwell when I change from Teva tablets to a different brand at my next prescription?

Most patients are unlikely to notice any change if they are switched from the Teva product to another levothyroxine product. However, if you start to feel unwell then you should see your doctor. You may not notice any changes for 4-6 weeks after switching to a different brand.

10. Will my levothyroxine dose need to be changed if I switch to or from the Teva make?

It is possible that your dose of levothyroxine will need adjustment. If you feel unwell, then you should see your doctor who will check whether a dose adjustment is needed. You may not notice any symptoms until within 4-6 weeks after changing from the Teva tablets to another make.

11. Where can I get more advice on this subject?

Patients should discuss any questions with their supervising healthcare professional.

Please also visit our website www.mhra.gov.uk

FAQs covering specific patient groups for whom control of thyroid function is particularly important.

Pregnancy

12. I am pregnant and I am taking thyroxine tablets. What shall I do?

Pregnant women with under-functioning thyroid are monitored with blood tests throughout pregnancy. Therefore, any need for adjustments to your daily dose of levothyroxine would have been recognised and addressed by your supervising healthcare professional. However, if you have recently been supplied with Teva levothyroxine 100mcg tablets, it is recommended that you make an early appointment (within a week) with your healthcare professional, so your thyroid status can be assessed. In the meantime, please continue to take your tablets as instructed by your doctor.

13. I am unsure whether I have taken these tablets in the past, would I have harmed myself or my baby?

Pregnant women with under-functioning thyroid are monitored with blood tests throughout pregnancy. Therefore, any need for adjustments to your daily dose of levothyroxine would have been recognised and addressed by your supervising healthcare professional. If in doubt, please see your healthcare professional.

Cardiac disease

14. I have heart disease (including angina, previous heart attack, previous stroke, previous heart surgery, palpitations or irregular heart rhythm, problems with circulation in extremities) and take Teva levothyroxine 100mcg tablets. Will I be affected?



Patients taking these tablets for some time will have been stabilised on them with blood tests. However if you have any deterioration in angina, breathlessness or palpitations, then you should make an early appointment with your healthcare professional for a clinical review and blood test. Your thyroid status should be carefully monitored once your doctor puts you on a different make of levothyroxine.

Thyroid cancer

15. I have had previous treatment for thyroid cancer and now take Teva levothyroxine 100mcg tablets. What should I do?

If you are taking Teva levothyroxine 100mcg tablets, please make an early appointment with your supervising healthcare professional for an assessment of the effectiveness of treatment. In the meantime, please continue to take your tablets as instructed by your doctor.