

Date: 13 May 2020

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Diprivan 10 mg/ml (1%) Emulsion for Injection or Infusion (propofol): Interim supply of Stock to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: Aspen Pharma Trading Limited is currently experiencing supply disruption with Diprivan 10 mg/ml (1%) Emulsion for Injection or Infusion (propofol), 50ml Pre-filled Syringes in the UK.

To ensure continuity in supply during the current Covid-19 situation, Aspen Pharma Trading Limited has obtained approval from the MHRA to supply normal UK product packed with the usual UK packaging except for the label on the tray inside the carton which comes in Chinese. The carton, leaflet, and pre-filled syringe label are all in the normal UK livery.

Batch: RG839, Exp: 31/10/2021, 22,221 packs in total.

Batch: RH112, Exp: 31/10/2021, 7,680 packs in total.

Please note the following:

- This product is considered licensed in the UK.
- The product has the same formulation as the UK product.
- The product is manufactured according to the same manufacturing process and relevant quality controls as the UK product.
- The only differences between these batches and UK product is that the tray lid label is in Chinese. The syringe label and carton have the same English text as the UK product but the carton 2D barcode does not function.
- Please ensure the UK Summary of Product Characteristics (SPC), and Patient Information Leaflet (PIL) in pack are followed.
- The MHRA has approved this product under a batch specific variation to the marketing authorisation.

To further assist in identification of the product, the Chinese tray lid label image is provided with this letter, along with the UK tray lid image which should be referred to in its place. The rest of the packaging is in the correct English livery.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.



Aspen Pharma Trading Limited

3016 Lake Drive, Citywest Business Campus
Dublin 24, Ireland Registration No 482868
Tel + 353 1 630 8400 Fax + 353 1 630 8401
www.aspenpharma.com

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website <https://www.gov.uk/yellowcard>, the free Yellow Card app available from the [Apple App Store](#) or [Google Play Store](#), and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effect can also be reported by calling 0800 731 6789 for free.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

Company contact point

If you have any questions about this letter or wish more information about Diprivan 10 mg/ml (1%) emulsion for injection or infusion (propofol), Pre-filled Syringe, please contact Aspen Pharma Trading Limited Medical Information on 01748828391, or

Aspenmedinfo@professionalinformation.co.uk.

Directors LA Hill (UK) K Szkudlarek (PL)
C Van Der Linde (SA)
Company Secretary NV De Klerk (SA)

Chinese Labels

丙泊酚乳状注射液

1%_{w/v}

得普利麻

10 / ml

50毫升含丙泊酚500毫克
玻璃预充注射器
 50ml:500mg 50ml/瓶

每支注射器只用于一位患者，不可重复使用。
 本品不含防腐剂，必须严格无菌操作。
 用后的剩余药物必须丢弃，此注射器不可用于抽取其他液体。

使用前请仔细阅读说明书，有效期：24个月。
 贮藏：2~25℃贮存，不得冷冻。
 预充于玻璃注射器中，使用前摇匀。
 将本品存放在远离儿童处。

进口药品注册证号：H20171275

装配说明见背面

只供一次性输注使用

Diprifusor和得普利麻ASPIN是阿斯特拉泽尼卡公司的商标。
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生产企业：Conferen Pharma S.p.A.
 Viale dell'Industria 3,
 20067 Caponago, Italy

P044487

Reserved for Variable Data

只供一次性输注使用

装配说明

维持无菌（针筒和活塞表面非无菌）

1. 取出玻璃注射器针筒并检查内容物，摇晃，取下塑料盖，酒精消毒橡胶封帽干。
2. 取出连接器，除去针帽。
3. 将注射器针筒垂直放置，将连接器完全固定在针筒前部蓝色密封盖上，使针头穿过密封橡胶。
4. 将针栓按顺时针方向放入针筒，注意：必须完全装入，否则由于虹吸作用，针栓可能掉出。
5. 排气（允许小气泡存在），连接输注导管，将组装好的注射器放置于与之相匹配的输注泵上。

使用前仔细阅读说明书

6. 预充注射器上有一识别标记，用于与Diprifusor输注泵配合使用。麻醉医生输入相应数据后，Diprifusor TCI输注系统将自动识别得普利麻的浓度并调整输注速率。

只供一次性输注使用

P044487

UK Labels

DIPRIVAN

propofol

10 mg/ml (1%)

Emulsion for injection or infusion

10 / ml

500mg propofol in 50ml

Also contains: Soya-bean Oil, Purified Egg Phosphatide, Glycerol, Sodium Hydroxide, Disodium Edetate, Water for Injections. See leaflet for further information.

50ml

Pre-filled syringe POM

For use in one patient only – NOT A MULTIDOSE CONTAINER. Does not contain preservatives – asepsis must be maintained. Any portion of the contents remaining after use **MUST** be discarded. This syringe should not be used for drawing up any fluid.

Read the package leaflet before use.
 Store between 2°C and 25°C. Do not freeze.
 SHAKE BEFORE USE. Glass syringe. Keep out of the sight and reach of children.

ASSEMBLY INSTRUCTIONS ON REVERSE

Trade Marks herein are the property of the AstraZeneca group.

FOR SINGLE USE INFUSION ONLY

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Aspen Pharma Trading Limited,
 3016 Lake Drive, Citywest Business Campus,
 Dublin 24, Ireland P045519

Reserved for Variable Data

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ASSEMBLY INSTRUCTIONS

MAINTAIN ASEPSIS

(Exterior of syringe and plunger non-sterile)

1. Remove glass syringe barrel from tray and check integrity. SHAKE. Remove the blue plastic cover. Clean the rubber septum with an alcohol spray or an alcohol-soaked swab. Allow alcohol to dry.
2. Remove luer connector from packaging. Pull off needle cover from luer connector.
3. Stand the syringe barrel vertically on a hard surface and push luer connector firmly on to syringe barrel so needle penetrates rubber seal and connector fully covers blue seal.
4. Add plunger rod by screwing clockwise. CAUTION: the rod must be fully screwed on, otherwise it may detach which could result in siphoning of the syringe contents.
5. Unscrew luer cover. Remove excess gas from the syringe (a small gas bubble may remain). Assemble administration line. Place assembled syringe in an appropriate infusion pump.

For information on use in a syringe pump see package leaflet.

6. The pre-filled syringes have a specific identification tag for use in syringe pumps incorporating 'Diprifusor'. The 'Diprifusor' TCI system will automatically adjust the infusion rate for the concentration of 'Diprivan' recognised, when the anaesthetist has input the appropriate information.

FOR SINGLE USE INFUSION ONLY