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Questions and answers on Durogesic and associated names (fentanyl transdermal patches)

Outcome of a procedure under Article 30 of Directive 2001/83/EC

On 21 July 2016, the European Medicines Agency completed a review of Durogesic. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that there is a need to harmonise the prescribing information for Durogesic in the European Union (EU).

What is Durogesic?

Durogesic is a medicine used to relieve severe long-term pain in adults and children from 2 years of age. It contains the active substance fentanyl and is available as a transdermal patch (a patch that gradually delivers the medicine through the skin). Fentanyl is an opioid (a pain medicine related to morphine).

Durogesic is available in the EU under various trade names including Durogesic DTrans and Durogesic Matrix. The company that markets these medicines is Janssen-Cilag and associated companies.

Why was Durogesic reviewed?

Durogesic has been authorised in the EU via national procedures. This has led to divergences across Member States in the way the medicine can be used, as seen in the differences in the summaries of product characteristics (SmPCs), labelling and package leaflets in the countries where the medicine is marketed.

Durogesic was identified as needing harmonisation by the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh)[1].

On 15 September 2015, the European Commission referred the matter to the CHMP in order to harmonise the marketing authorisations for Durogesic in the EU[2].

[1] The CMDh is a medicines regulatory body representing the European Union (EU) Member States, Iceland, Liechtenstein and Norway
[2] This referral procedure did not cover other fentanyl formulations such as tablets, nasal sprays or solutions for injection

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What are the conclusions of the CHMP?

The CHMP, in the light of the data submitted and the scientific discussion within the Committee, was of the opinion that the SmPCs, labelling and package leaflets should be harmonised across the EU.

The areas harmonised include:

4.1 Therapeutic indications

The CHMP agreed that Durogesic can be used in adults to treat severe long-term pain that requires continuous treatment with opioid medicines, whether or not the pain is caused by cancer. Durogesic can also be used to treat severe long-term pain in children from 2 years of age who are already being treated with opioids.

4.2 Posology and method of administration

Having harmonised the indication, the CHMP also harmonised the recommendations on how to use Durogesic. The appropriate starting dose should be chosen according to the patient's current use of opioid medicines. The age and general condition of the patient should also be taken into account. The dose should be re-assessed regularly during treatment and the lowest effective dose should be used. The patch should be replaced every 3 days.

Tables to work out the appropriate dose of Durogesic when switching from other opioids taken by mouth or given by injection have been included in the harmonised SmPC.

The use of Durogesic is not recommended in patients who have not taken opioid medicines before. However, adult patients who cannot take opioids by mouth and for whom Durogesic is considered the only option could be given the patch with the lowest dose. These patients should be closely monitored for side effects.

4.3 Contra-indications

Durogesic must not be used to relieve severe short-term pain or pain resulting from an operation. Also, it must not be used in patients with severe respiratory depression (breathing problems), or in those allergic to fentanyl or any other ingredients of Durogesic.

4.4 Special warnings and precautions for use

Patients who have serious side effects with Durogesic should be monitored for at least 24 hours after removal of the patch, depending on their symptoms, because the active substance fentanyl remains in the blood for some time and its level only declines slowly (by about half after 24 hours).

Durogesic patches release enough fentanyl to be fatal if not used appropriately, especially for a child; sufficient fentanyl remains in the patch to cause severe effects even after it has been used. Therefore, the patches must be kept out of the sight and reach of children, before and after use. In children treated with Durogesic, the patch should be applied on the upper back to prevent the child from removing the patch.

This section also contains other warnings, including warnings about the risk of respiratory depression, dependence and potential for abuse, and use in children and elderly patients.

Other changes

The Committee also harmonised other sections of the SmPC including sections 4.6 (fertility, pregnancy and lactation), 4.8 (side effects), and 4.9 (overdose).

The amended information to doctors and patients is available here.

The European Commission issued a decision on this opinion on 22/9/16.