LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Summary Public Assessment Report

Fentasub 67 µg, 133 µg, 267 µg, 400 µg, 533 µg and 800 µg sublingual tablets
Fentanyl citrate

SE/H/1315/01-06/DC

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Summary Public Assessment Report

Fentasub

(fentanyl citrate)

Sublingual tablets

This is a summary of the public assessment report (PAR) for Fentasub. It explains how Fentasub was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Fentasub.

For practical information about using Fentasub, patients should read the package leaflet or contact their doctor or pharmacist.

What is Fentasub and what is it used for?

Fentasub is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substance, but is available as sublingual tablets, which is a different pharmaceutical form than the reference product.

The company has provided additional own data to demonstrate the safety and efficacy of Fentasub regarding this difference from the reference medicine.

The reference medicine for Fentasub is Leptanal.

Fentasub is used to treat breakthrough pain in adult patients with cancer who are already taking other opioid pain medicines for their persistent (around-the-clock) cancer pain.

Breakthrough pain is additional, sudden pain that occurs even though you have taken your usual opioid pain-relieving medicines.

How does Fentasub work?

Fentasub contains the active ingredient fentanyl, which belongs to a group of strong pain-relieving medicines called opioids.

How is Fentasub used?

The pharmaceutical form of Fentasub is sublingual tablets for sublingual use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Fentasub have been shown in studies?

Because Fentasub is a hybrid application of Leptanal, clinical studies have been provided for Fentasub to show efficacy for the difference of Fetasub from the reference product Leptanal.

What are the possible side effects of Fentasub?

For the full list of all side effects reported with Fentasub, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Fentasub approved?

This medicine is similar to a reference medicine containing the same active substance, but is available as sublingual tablets. The company has provided additional own data to demonstrate the safety and efficacy of Fentasub regarding this difference from the reference medicine. No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Fentasub's benefits are greater than its risks and recommended that it be approved for use.

What measures are being taken to ensure the safe and effective use of Fentasub?

A risk management plan has been developed to ensure that Fentasub is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Fentasub, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Fentasub

The marketing authorisation for Fentasub was granted on 2013-10-31 in Sweden.

The full PAR for Fentasub can be found on the following website: http://mri.medagencies.org/Human/. For more information about treatment with Fentasub, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2013-10.