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Dzuveo (*sufentanil*)

An overview of Dzuveo and why it is authorised in the EU

What is Dzuveo and what is it used for?

Dzuveo is an opioid pain medicine used to treat moderate to severe pain in adults.

It is a 'hybrid medicine'. This means that it is similar to a 'reference medicine' (called Sufenta Forte) containing the same active substance. The difference between the products is that Dzuveo is available as sublingual tablets (tablets to be dissolved under the tongue) while the reference medicine is a solution for injection.

Dzuveo contains the active substance sufentanil.

How is Dzuveo used?

Dzuveo is available as 30 µg sublingual tablets. Using a disposable applicator, the healthcare professional should place one tablet under the patient's tongue and leave it to dissolve. The tablet must not be chewed or swallowed.

Patients should not eat or drink and should talk as little as possible for the 10 minutes after taking the tablet. They can be given the tablets as needed but should wait at least one hour after one tablet before having another. Dzuveo should not be used for more than 48 hours.

Dzuveo can only be obtained with a prescription. It should be given by a healthcare professional experienced in treating pain and in a place (such as a hospital) where the patient can be monitored. For more information about using Dzuveo, see the package leaflet or contact your doctor or pharmacist.

How does Dzuveo work?

The active substance in Dzuveo, sufentanil, is an opioid that works by attaching to receptors (targets) in the brain known as µ-opioid receptors. Attaching to these receptors in the brain helps relieve the patient's pain.

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What benefits of Dzuveo have been shown in studies?

Two main studies have shown that Dzuveo left to dissolve under the tongue is effective at reducing severe pain following surgeries. Both studies used a pain rating scale known as SPID12 which tracks reduction in pain over 12 hours.

In the first study in 163 patients who had undergone abdominal surgery, pain reduced by 26 points with Dzuveo compared with 13 points with placebo (a dummy treatment). In the second study in 101 patients after foot surgery, pain reduced by around 6 points with Dzuveo and increased by around 7 points with placebo.

What are the risks associated with Dzuveo?

The most serious side effects with sufentanil are severe breathing problems, which occur in around 6 people in 1,000. The most common side effects (which may affect more than 1 in 10 people) are nausea, vomiting and fever.

Dzuveo must not be used in patients with serious lung or breathing problems. For the full list of side effects and restrictions with Dzuveo, see the package leaflet.

Why is Dzuveo authorised in the EU?

Studies show that Dzuveo is effective at reducing severe pain following surgeries. The side effects seen with Dzuveo are those expected with opioids, and are considered manageable. The European Medicines Agency therefore decided that Dzuveo's benefits are greater than its risks and it can be authorised for use in the EU.

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

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Dzuveo have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Dzuveo are continuously monitored. Side effects reported with Dzuveo are carefully evaluated and any necessary action taken to protect patients.

Other information about Dzuveo

Dzuveo received a marketing authorisation valid throughout the EU on 25 June 2018.

Further information on Dzuveo can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports.

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