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EPAR summary for the public

Zubsolv

buprenorphine / naloxone

This is a summary of the European public assessment report (EPAR) for Zubsolv. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Zubsolv.

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

What is Zubsolv and what is it used for?

Zubsolv is a medicine used in adults and adolescents aged over 15 years to treat dependence on opioid (narcotic) drugs such as heroin or morphine.

Zubsolv is used in individuals who are also receiving medical, social and psychological support and who have agreed to be treated for their addiction. It contains the active substances buprenorphine and naloxone.

Zubsolv is a 'hybrid medicine'. This means that it is similar to a 'reference medicine' containing the same active substances, but Zubsolv contains these at different strengths. The reference medicine for Zubsolv is Suboxone.

How is Zubsolv used?

Because Zubsolv can be misused or cause addiction, it can only be obtained by 'special' prescription and must be used under the supervision of a doctor who has experience in the management of opioid addiction.

Zubsolv is available as tablets of various strengths (0.7 mg/0.18 mg, 1.4 mg/0.36 mg, 2.9 mg/0.71 mg, 5.7 mg/1.4 mg, 8.6 mg/2.1 mg, 11.4 mg/2.9 mg). The tablets are taken once a day by placing them under the tongue and allowing them to dissolve for up to 10 minutes.

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On the first day of treatment, the recommended daily dose is one or two tablets of Zubsolv 1.4 mg/0.36 mg or 2.9 mg/0.71 mg. During the next days, the doctor may increase the dose depending on the patient's response, but the daily dose should not be higher than 17.2 mg buprenorphine. Once the patient has been stabilised, the maintenance dose may be reduced gradually if the patients agrees, and eventually treatment may be stopped.

For more information, see the package leaflet.

How does Zubsolv work?

Zubsolv contains two active substances: buprenorphine, a partial opioid agonist (it acts like an opioid drug but less powerfully), and naloxone, an opioid antagonist (it counteracts the effects of opioid drugs).

Sublingual tablets containing buprenorphine alone have been available in the EU since the mid-1990s for the treatment of opioid addiction. However, buprenorphine tablets have been misused by drug addicts who dissolve the tablets and inject themselves with the resulting solution. The addition of naloxone helps prevent the misuse of the medicine. This is because, when injected, naloxone counteracts the effects of opioids, causing the patient to experience acute withdrawal symptoms.

What benefits of Zubsolv have been shown in studies?

The company provided data from studies with the reference medicine Suboxone and from the published literature showing the benefits of buprenorphine and naloxone in the treatment of opioid dependence.

A study involving 125 healthy volunteers showed that some strengths of the Zubsolv tablets produced a lower level of the active substances in the body than the reference product and therefore the two medicines cannot be used interchangeably. The study also showed that Zubsolv tablets dissolved faster and had a better taste than the reference medicine.

What are the risks associated with Zubsolv?

The most common side effects with Zubsolv (which may affect more than 1 in 10 people) are constipation and symptoms of drug withdrawal such as insomnia (difficulty sleeping), headache, nausea (feeling sick), hyperhidrosis (excessive sweating) and pain. Serious side effects include seizures (fits), vomiting, diarrhoea and abnormal results of blood tests for liver function. For the full list of side effects reported with Zubsolv, see the package leaflet.

Zubsolv must not be used in patients with severe respiratory insufficiency (inability to breathe properly), severe liver problems, acute alcoholism (excessive alcohol consumption) or delirium tremens (a condition caused by alcohol withdrawal). It must also not be used with the medicines naltrexone and nalmefene, other opioid antagonists used for the treatment of alcohol or opioid dependence. For the full list of restrictions, see the package leaflet.

Why is Zubsolv approved?

Combining buprenorphine and naloxone is an established strategy for managing opioid dependence which prevents misuse of the medicine. As for Suboxone, the European Medicines Agency decided that Zubsolv's benefits are greater than its risks and recommended that it be approved for use in the EU. Since Zubsolv does not produce the same amounts of buprenorphine and naloxone in the blood as the reference medicine, the medicines cannot be used interchangeably.

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

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

Other information about Zubsolv

The European Commission granted a marketing authorisation valid throughout the European Union for Zubsolv on 10 November 2017.

The full EPAR for Zubsolv can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Zubsolv, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 11-2017.