Package leaflet: Information for the user

Exembol 1 mg/ml solution for infusion

argatroban monohydrate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
• Keep this leaflet. You may need to read it again.
• If you have any further questions, ask your doctor.
• If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Exembol is and what it is used for

Exembol is an anticoagulant (a drug that helps to prevent blood clots from forming in your blood circulation). It works by blocking the action of thrombin, a substance in your blood that is important in blood clotting.

Exembol is used if you are suffering from a disorder known as heparin-induced thrombocytopenia type II (HIT type II). If you have HIT type II, you are at risk of developing blood clots in your blood circulation that can cause heart attacks, stroke, breathing problems and problems with the blood supply to your limbs. Exembol can prevent these problems or prevent them from becoming worse.

2. What you need to know before you use Exembol

Do not use Exembol

Exembol will not be given to you:

• If you have uncontrolled bleeding
• If you are allergic (hypersensitive) to argatroban or to any of the other ingredients of Exembol
• If you have severely impaired liver function

Warnings and precautions

Exembol will be given to you with special care:

• If there is an increased risk of bleeding
• If you have recently had injections or infusions of other anticoagulants such as heparin
• If you have liver disease

Children and Adolescents

It is not advised to give this medicine to children or adolescents as the safe or effective dose of Exembol has not been clearly established.

Other medicines and Exembol

Please tell your doctor if you are taking, have recently taken, or might take any other medicines,

including medicines obtained without prescription.

Combined use with other blood thinning or blood clot dissolving medicines can increase the risk of bleeding.

Because Exembol contains ethanol, this can influence the effect of other medicines containing metronidazole (for infections) or disulfiram (for alcoholism).

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, you should ask your doctor for advice before Exembol is given to you.

As a precautionary measure, it is preferable to avoid the use of Exembol during pregnancy.

Avoid breast-feeding while you are being given Exembol (see also "Exembol contains alcohol").

Driving and using machines

Since Exembol contains alcohol you should not drive a car or use machines in connection with the treatment (see also "Exembol contains alcohol").

Exembol contains alcohol

This product contains 4 mg/ml or 0.5% by volume of alcohol (ethanol). The daily dose may therefore contain up to 5 ml (4 g) of alcohol, corresponding to 100 ml beer or 40 ml wine. This may be harmful for persons suffering from liver disease, alcoholism or epilepsy as well as for pregnant and nursing women and their children.

If you are pregnant or breast-feeding, talk to your doctor or pharmacist before taking this medicine.

If you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine.

The amount of alcohol in this medicine is not likely to have an effect in adults and adolescents, and its effects in children are not likely to be noticeable. It may have some effects in younger children, for example feeling sleepy.

The alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines.

Because this medicine is usually given slowly over several hours, the effects of alcohol may be reduced.

Exembol contains sorbitol

This medicine contains 150 mg sorbitol in each vial (50 ml) which is equivalent to 3 mg/ml.

Sorbitol is a source of fructose. If you (or your child) have hereditary fructose intolerance (HFI), a rare genetic disorder, you (or your child) must not receive this medicine. Patients with HFI cannot break down fructose, which may cause serious side effects.

You must tell your doctor before receiving this medicine if you (or your child) have HFI or if your child can no longer take sweet foods or drinks because they feel sick, vomit or get unpleasant effects such as bloating, stomach cramps or diarrhoea.

Exembol contains sodium

This medicine contains 177 mg sodium (main component of cooking/table salt) per vial (50 ml). This is equivalent to 9% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Exembol

Exembol will always be given to you by medical personnel. Exembol will be given to you intravenously (into a vein) by continuous infusion. The doctor will decide the dose and how long you will be treated.

4. Possible side effects

Like all medicines, Exembol can cause side effects, although not everybody gets them.

The most common side-effects are bleeding. Major bleeding can occur in about 5% of patients and minor bleeding in about 39% of patients. **You must tell your doctor immediately** if you experience any of the following symptoms:

- bleeding or bruising,
- blood in urine or stools
- vomiting or coughing up blood
- black stools
- difficulty in breathing
- cold sweaty skin
- dry mouth
- dilated pupils and/or weak rapid pulse.

These symptoms could indicate that you are experiencing bleeding problems.

Common side effects *(may affect up to 1 in 10 people):*
- anaemia
- blood clotting
- bleeding, including numerous small bleedings in skin and mucus membranes (purpura)
- nausea

Uncommon side effects *(may affect up to 1 in 100 people):*
- infections such as urinary tract infection
- changes in blood values
- blood clotting
- lack of appetite
- low blood sugar levels
- low sodium levels in the blood
- confusion
- dizziness
- fainting
- headache
- stroke
- muscle disorders
- speech disorder
- vision problems
- deafness
- heart attack
- fluid in the heart sac
- abnormal heart rhythm

- fast heartbeat
- low blood pressure
- high blood pressure
- inflammation of veins
- shock
- reduced oxygen supply to the tissues
- breathing difficulties
- fluid around the lungs
- hiccup
- blood in cough, vomit or stools
- constipation
- diarrhoea
- stomach inflammation
- difficulty in swallowing
- tongue disorder
- abnormal liver function
- jaundice (yellowing of the skin and eyes)
- changes in blood tests for liver function
- rash including nettle rash
- itching
- increased sweating
- hair loss
- muscle weakness
- muscle pain
- kidney failure
- fever
- pain
- tiredness
- injection site reactions
- swelling of the legs
- increased wound drainage
- abnormal laboratory results.

Not known *(frequency cannot be estimated from the available data).*
Cases of bleeding into the brain have been reported,

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Exembol

Keep this medicine out of the sight and reach of children.
Keep vial in the outer carton in order to protect from light.
Do not refrigerate or freeze.
The solution should be used immediately after opening.
In-use the solution should not be exposed to direct sunlight.
Solutions should not be used if they are cloudy or contain any particles.
Do not use Exembol after the expiry date which is stated on the carton/vial after "EXP". The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Exembol contains
The active substance is argatroban monohydrate 1 mg/ml.

1 ml solution for infusion contains 1 mg argatroban monohydrate.

1 vial with 50 ml solution for infusion contains 50 mg argatroban monohydrate.

The other ingredients are anhydrous ethanol, sorbitol, sodium chloride and water for injections.

This medicinal product must not be mixed with other medicinal products.

What Exembol looks like and contents of the pack
This medicinal product is a clear colourless to pale yellow solution for infusion. Each vial contains 50 ml of solution and the vials are packed in cardboard boxes of 4 or 12 vials.

Not all pack sizes may be marketed.

Marketing authorisation holder
Ethypharm, 194, Bureaux de la Colline, Bâtiment D,
92213 Saint-Cloud cedex, France.

Manufacturer
Central Pharma (Contract Packing) Limited
Caxton Road
Bedford
MK41 0XZ
United Kingdom

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:
United Kingdom : Macarthys Laboratories Ltd
email: medinfo@ethypharm.com

This medicinal product is authorised in the Member States of the EEA under the following

names:

Austria	Argatra
France	Arganova
Germany	Argatra
Sweden	Novastan
United Kingdom	Exembol

This leaflet was last revised in: October 2024

The following information is intended for healthcare professionals only.

Instructions for use, handling and disposal

Exembol 1 mg/ml Solution for Infusion is ready to use and requires no dilution before administration. It is recommended for use with a syringe driver to control the rate of administration.

The drug product is unpreserved and intended for single use only. The solution should be used immediately after opening. Any unused solution should be discarded.

If the solution is cloudy, or if an insoluble precipitate is noted, the vial should be discarded.

Light resistant measures such as foil protection for intravenous lines are not necessary. No significant potency losses have been noted following simulated delivery of the solution through intravenous tubing.

Any unused product or waste material should be disposed of in accordance with local requirements.