

B. PACKAGE LEAFLET

Package leaflet: Information for the patient

Byfavo 20 mg powder for solution for injection remimazolam

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you are given 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 or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Byfavo is and what it is used for
2. What you need to know before you are given Byfavo
3. How Byfavo is given
4. Possible side effects
5. How Byfavo is stored
6. Contents of the pack and other information

1. What Byfavo is and what it is used for

Byfavo is a medicine that contains the active substance remimazolam. Remimazolam is one of a group of substances known as benzodiazepines.

Byfavo is a sedative given before a medical test or procedure to make you feel relaxed and sleepy (sedated).

2. What you need to know before you are given Byfavo

You must not be given Byfavo if:

- you are allergic to remimazolam or other benzodiazepines (such as midazolam) or any of the other ingredients of this medicine (listed in section 6).
- you have an unstable form of a condition called myasthenia gravis (weakness of muscles) in which your chest muscles that help you breathe get weak

Warnings and precautions

Talk to your doctor or nurse before using Byfavo if you have any severe illness or condition and in particular if:

- you have very low or very high blood pressure or tend to faint
- you have heart problems especially a very slow and/or irregular (arrhythmic) heart rate
- you have any breathing problems including shortness of breath
- you have severe liver problems.
- you have a condition called myasthenia gravis in which your muscles are weak

Byfavo can cause temporary loss of memory. Your doctor will assess you before you leave the hospital or clinic and give you necessary advice.

Children and adolescents

Byfavo should not be given to patients under the age of 18 years because it has not been tested in children and adolescents.

Other medicines and Byfavo

Tell your doctor if you are taking, have recently taken or might take any other medicines, in particular about:

- opioids (including painkillers such as morphine, fentanyl and codeine or certain cough medicines or medicines for use in drug substitution therapy)
- antipsychotics (medicines to treat certain psychiatric illnesses)
- anxiolytics (tranquilizers or medicines that reduce anxiety)
- medicines that cause sedation (for example temazepam or diazepam)
- antidepressants (medicines to treat depression)
- certain antihistamines (medicines to treat allergies)
- certain antihypertensives (medicines to treat high blood pressure)

It is important to tell your doctor or nurse if you are taking other medicines, as using more than one at the same time can change the effect of the medicines involved.

Byfavo with alcohol

Alcohol can change the effect of Byfavo. Tell your doctor or nurse:

- how much alcohol you drink regularly or if you have had problems with alcohol use;
- if you have drunk alcohol in the last 24 hours.

Do not drink alcohol for 24 hours before you are given Byfavo.

Pregnancy and breast-feeding

You should not use Byfavo if you are pregnant or think you may be pregnant. Tell your doctor or nurse if you are pregnant or think you may be pregnant.

If you are a breastfeeding mother, do not breastfeed for 24 hours after you are given this medicine.

Driving and using machines

Byfavo makes you sleepy, forgetful and affects your ability to concentrate. Even though these effects wear off rapidly, you must not drive and operate machinery until these effects are completely gone. Ask your doctor about when you can drive or operate machinery again.

Byfavo contains dextran 40 for injection

This medicine contains 79.13 mg of dextran 40 for injection in each vial. Rarely, dextrans can cause severe allergic reactions. If you have breathing difficulty or swelling or you feel faint, get medical help at once.

3. How Byfavo is given

Your doctor will decide on the right dose for you.

Your breathing, heart rate and blood pressure will be monitored during the procedure and the doctor will adjust the dose if needed.

A doctor or nurse will give you Byfavo by injection into your vein (blood stream) before and during your medical test or procedure. Byfavo is mixed with sterile saline to make a solution before it is used.

After the procedure

Your doctor or nurse will check on you for a while after sedation to make sure that you feel well and are fit to go home.

If you are given too much Byfavo

If you are given too much Byfavo, you may have the following symptoms:

- you may feel dizzy
- you may get confused
- you may feel sleepy
- your eyesight may get blurry or you may have involuntary eye movements (dancing eyes)
- you may get agitated
- you may feel weak
- your blood pressure may drop
- your heartbeat may slow down
- your breathing may become slow and shallow
- you may lose consciousness

Your doctor will know how to treat you.

Ask your doctor or nurse if you have any questions about the use of this medicine.

4. Possible side effects

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

Very common (*may affect more than 1 in 10 users*)

- Low blood pressure
- Unusually slow or shallow breathing (and low oxygen level in blood)

Common (*may affect up to 1 in 10 users*)

- Headache
- Feeling dizzy
- Slow heart rate
- Feeling sick (nausea)
- Being sick (vomiting)

Uncommon (*may affect up to 1 in 100 users*)

- Sleepiness
- Feeling cold
- Chills
- Hiccups

Not known (*frequency cannot be estimated from the available data*)

- sudden, severe allergic reaction

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme, Website: 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 Byfavo is stored

Professionals in the hospital or clinic are responsible for storing this medicine.

6. Contents of the pack and other information

What Byfavo contains

- The active substance is remimazolam. Each vial contains remimazolam besylate equivalent to 20 mg of remimazolam. After reconstitution each mL contains 2.5 mg of remimazolam.
- The other ingredients are:
 - Dextran 40 for injection
 - Lactose monohydrate
 - Hydrochloric acid
 - Sodium hydroxide

See section 2, “Byfavo contains dextran 40 for injection”.

What Byfavo looks like and contents of the pack

Byfavo is a white to off-white powder for solution for injection.

Pack sizes

10 vial pack

Marketing Authorisation Holder

PAION Deutschland GmbH
Heussstraße 25
52078 Aachen
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Manufacturer

PAION Netherlands B.V.
Vogt 21
6422 RK Heerlen
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