

Hexvix

Powder for intravesical solution and diluent 85 mg

Hexaminolevulinate (as hydrochloride)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Hexvix powder for intravesical solution and diluent.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. In deciding to give you Hexvix, your doctor has weighed the risks of you taking Hexvix against the benefits it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with this medicine.

You may need to read it again.

What Hexvix is used for

Hexvix is for diagnostic use only.

Hexvix blue light fluorescence cystoscopy is used as an adjunct to standard white light cystoscopy to contribute to the diagnosis and management of bladder cancer in patients with known or high suspicion of bladder cancer.

Hexvix is not recommended for use in children.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor or pharmacist if you have any questions about why this medicine has been prescribed for you.

Before you take it

When you must not use Hexvix

- 1. Do not use Hexvix if you are allergic to hexaminolevulinate hydrochloride or any of the ingredients listed at the end of this leaflet.**
- 2. Do not use Hexvix if you have been diagnosed with porphyria.**
- 3. Do not use Hexvix if you are suffering from haematuria or blood in the urine.**
- 4. Do not use Hexvix if you have bladder inflammation, a recent urinary tract infection or BCG treatment.**
- 5. Do not use Hexvix if you are pregnant or intending to get pregnant.**
- 6. Do not breastfeed if you are using Hexvix as the drug may be found in breast milk.**

Talk to your doctor if you are unsure whether you have any of the conditions listed above.

Do not use Hexvix after the expiry (EXP) printed on the pack.

If you use the medicine after the expiry date has passed, it may not work as well.

Do not use Hexvix if the packaging is torn or shows signs of tampering.

Do not use it to treat any other complaint unless your doctor says it is safe. Do not give this medicine to anyone else.

Before you start to use Hexvix

Tell your doctor if you are pregnant or intend to become pregnant.

Tell your doctor if you are breastfeeding or planning to breastfeed.

Tell your doctor if you have or have had any medical conditions, especially the following:

- Porphyria
- Bladder inflammation, urinary tract infection or recent BCG treatment.
- Haematuria or blood in urine.

If you have not told your doctor about any of the above, tell them before you use this medicine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.

Some medicines may be affected by Hexvix, or may affect how well Hexvix works.

You need to tell your doctor if you are using any other medicines.

If you are unsure whether you are taking one of the drugs that may interact with Hexvix, ask your doctor or pharmacist.

Your doctor or pharmacist can tell you what to do if you are taking any of such medicines.

If you have not told your doctor about any of these things, tell them before you take Hexvix.

How to use Hexvix

How to give it

Hexvix powder for intravesical solution and diluent will only be given in hospitals by qualified practitioners.

The bladder has to completely empty before instilling Hexvix.

The powder will be reconstituted with the entire contents of diluent.

50 mL of the reconstituted solution is instilled into the bladder through a catheter. You are required to retain the fluid for approximately 60 minutes.

Following evacuation of the bladder, the cystoscopic examination in blue light will start within approximately 60 minutes. The cystoscopic examination will not be performed more than 3 hours after Hexvix is instilled in the bladder.

For optimal visualisation your physician will examine and map the entire bladder under both white and blue light before any surgical measures are initiated. Biopsies of all mapped lesions will normally be taken under white light and complete resection will be verified by switching to blue light.

How much to give

The entire content of the reconstituted solution is required to be given each time.

While you are using Hexvix

Things you must do

Be sure to keep all of your doctor appointments so that your progress can be checked.

Tell all the doctors, dentists and pharmacists who are treating you that you were administered with Hexvix.

Tell your doctor if you become or intend to become pregnant while using Hexvix.

Things you must not do

Do not use Hexvix for any other purpose.

Do not give this medicine to anyone else, even if they have the same condition as you.

Things to be careful of

If you are going to have surgery, tell the anaesthetist that you have used Hexvix.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while using Hexvix.

All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Tell your doctor if you notice any of the following and they worry you:

- Headache
- Nausea
- Vomiting
- Constipation
- Diarrhoea
- Bladder spasm or contraction of the bladder without warning causing an urgent need to release urine or bladder incontinence
- Bladder pain
- Dysuria or painful or difficult urination
- Urinary retention or inability to completely empty the bladder
- Haematuria or presence of blood in the urine
- Pyrexia or fever
- Post procedural pain

Tell your doctor immediately if you notice any of the following:

- Bladder spasm

- Bladder pain
- Blood in urine
- Painful or difficulty in urination

These may be serious side effects of Hexvix.

If any of the above symptoms occurs or you suspect any other drug reaction, please consult your doctor immediately.

Other side effects not listed above may also occur in some patients.

Tell your doctor if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Your doctor will monitor you very carefully for side effects.

After using Hexvix

Storage

Hexvix should be stored at 25°C.

It should be used immediately after reconstitution. If storage is necessary, hold at 2-8 °C for not more than 2 hours. The reconstituted solution, if stored at 2 – 8°C, should be allowed to warm to room temperature before instilling into the bladder.

Product description

What it looks like

Hexvix is provided as a kit containing 1 vial of the powder and 1 container of the diluent.

Hexvix powder is a sterile, freeze-dried white to off-white or pale yellow powder. Each vial contains 100 mg of Hexaminolevulinate hydrochloride, equivalent to 85mg of the active ingredient hexaminolevulinate.

The diluent for reconstitution is a sterile, clear, colourless solution.

Ingredients

Powder

Active Ingredient:

hexaminolevulinate (as hydrochloride) 85mg.

Other Ingredients:

There are no excipients.

Diluent contains:

- dibasic sodium phosphate dehydrate,
- monobasic potassium phosphate
- sodium chloride,
- hydrochloric acid,
- sodium hydroxide and
- water for injections.

Manufacturer

Hexvix is supplied in Australia by:

Juno Pharmaceuticals Pty Ltd
Level 2, 6 Bond Street,
South Yarra, VIC – 3141

This leaflet was prepared in August 2016.