

JAVLOR 25 mg/mL Concentrated Injection

vinflunine ditartrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Javlor.

It does not contain all the available information.

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

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Javlor against the benefits this medicine is expected to have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What Javlor is used for

Javlor is used to treat cancer of the bladder and urinary tract at an advanced stage. Javlor is given if previous therapy with a platinum-containing medicine has failed.

Javlor belongs to a group of medicines called antineoplastic or cytotoxic medicines. You may also hear of these medicines being called chemotherapy.

Javlor contains the medicine, vinflunine which belongs to a family of medicines called vinca alkaloids. Javlor works by stopping cancer cells from growing and multiplying causing the cells to die.

Your doctor may have prescribed Javlor for another purpose.

Ask your doctor if you have any questions about why Javlor has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you are given Javlor

When you must not be given it

Do not take Javlor if you have an allergy to the active substance, vinflunine or to the other vinca alkaloids, (vinblastine, vincristine, vindesine, vinorelbine).

Symptoms of an allergic reaction to Javlor may include:

- shortness of breath
- wheezing, difficulty breathing or a tight feeling in your chest
- swelling of the face, lips, tongue or other parts of the body
- rash, itching, hives or flushed, red skin.

Do not take Javlor if you have or have had (within the last two weeks), a severe infection.

Tell your doctor if you have or have had a severe infection in the last two weeks. Your doctor may decide to delay your treatment until the infection has gone.

Do not breastfeed while being treated with Javlor.

Javlor may pass into breastmilk and therefore there is a possibility that the breastfed baby may be affected.

Do not have Javlor after the expiry date printed on the pack. The expiry date refers to the last day of that month.

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

Do not have Javlor if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start having Javlor, talk to your doctor.

Before you are given it

Javlor is a potent cytotoxic drug that results in a decrease in blood cells. Your blood count will be carefully monitored before and during your treatment.

Tell your doctor if you have allergies to:

- any other medicines;
- any other substances, such as foods, preservatives or dyes.

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

- heart problems including chest pain and heart attack).
- liver problems.

- kidney problems.
- a low white blood cell count which you may notice as signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers.
- constipation.
- stomach problems (including surgery on your stomach).
- cancer of the peritoneum (the membrane lining the stomach wall, covering the liver, stomach, spleen, gallbladder and intestines).

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

Like most medicines used to treat cancer, Javlor is not recommended for use in pregnancy unless it is strictly necessary. Javlor may affect your developing baby if you take it during pregnancy. If there is a need to consider Javlor during your pregnancy, your doctor will discuss with you the benefits and risks of using it. Genetic counselling is also recommended.

If you are a fertile man or woman, you should use an effective method of contraception during your treatment with Javlor and for three months after your last dose of Javlor.

Tell your doctor if you wish to have children after your therapy with Javlor.

It is recommended that you seek genetic counselling if you wish to have children after your therapy with Javlor.

If you intend to father a child, seek advice on sperm storage before starting your therapy because of the possibility that Javlor may cause permanent infertility.

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

You should not breastfeed while you are being treated with Javlor.

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 shop.

Tell your doctor if you are taking medicines for pain called opiates. If you are taking opiates at the same time as having Javlor, you may need treatment to avoid constipation.

Some medicines and Javlor may interfere with each other.

These include:

- ketoconazole and itraconazole, medicines used to treat fungal infections;
- retonavir, a medicine used to treat HIV and AIDS;
- pegylated doxorubicin a medicine used to treat cancer;
- rifampicin, a medicine used to treat tuberculosis or meningitis;
- a herbal treatment for depression called St John's wort or *Hypericum perforatum*.

These medicines may be affected by Javlor or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or to avoid while taking Javlor.

You should also tell your doctor if you are drinking grapefruit juice. Grapefruit juice can also interfere with the effectiveness of Javlor.

If you have not told your doctor about any of the above, do so before you begin treatment with Javlor.

How Javlor is given

How much is given

Your doctor will decide what dose you will receive. This depends on your body surface area, your age, your condition and factors such as your liver and kidney function and whether you have had prior irradiation of the pelvis.

Your doctor may adjust your dose during treatment.

Javlor reduces the number of white blood cells in the body. Your doctor will check these levels regularly. Further doses of Javlor may be delayed until your blood cell numbers return to acceptable levels.

How it is given

Javlor is first diluted before it is given by intravenous infusion, i.e. a slow injection into your veins, lasting 20 minutes. The treatment is repeated every 3 weeks.

Before receiving Javlor, you may be given laxatives and other treatments to prevent constipation and antiemetic medicines to prevent vomiting.

Javlor must only be given by a doctor or nurse experienced in the use of chemotherapy medicines.

How long it is given

Your doctor will decide how many doses you will need.

If you miss a dose

Tell your doctor as soon as possible if you realize that you have missed an appointment for receiving your dose of Javlor.

If you have problems remembering when your next dose is due, use a diary or calendar or ask a friend to remind you.

Overdose

As Javlor is given to you under the supervision of your doctor, it is very unlikely that you will receive too much. However, if you experience any side effects while or after being given Javlor, tell your doctor, nurse or pharmacist.

Symptoms of a Javlor overdose include the side effects listed below in the "Side effects" section, but are usually of a more severe nature.

While you are being given Javlor

Things you must do

Tell your doctor or nurse immediately if you feel any pain or discomfort during the injection.

Tell your doctor or nurse if you experience any neurological symptoms such as headaches, loss of energy, fatigue, confusion, convulsions or altered consciousness.

Keep all follow-up appointments with your doctor.

It is important to have your follow-up doses of Javlor at the appropriate times to get the best effects from your treatment.

Your doctor will also need to do some blood and other tests from time to time to check on your progress and monitor any unwanted side effects.

Tell any other doctors, dentists and pharmacists who are treating you that you are receiving treatment with Javlor.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are receiving treatment with Javlor.

If you become pregnant while taking Javlor, tell your doctor immediately.

Taking Javlor during pregnancy is not recommended. Your doctor will discuss with you the risks and benefits of using Javlor when pregnant and decide whether or not treatment should be continued.

Things to be careful of

Be careful driving or operating machinery until you know how Javlor affects you.

If you experience symptoms that affect your ability to concentrate and react, do not drive a car or operate machinery. Dizziness and fainting are common side effects of Javlor.

Side effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are taking Javlor.

Like other medicines that treat cancer, Javlor can cause side effects, some of which may be serious. You may need medical treatment if you get some of these side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

- constipation;
- diarrhea;
- nausea;
- vomiting;
- weight loss;
- weight gain;
- loss of appetite;
- muscle pain;
- unusual tiredness, weakness, sleepiness, drowsiness or lack of energy;
- unusual hair loss or thinning;
- pain at the site of injection;
- headache;

- aching muscles, muscle tenderness or weakness, not caused by exercise;
- jaw pain;
- joint pain; painful swollen joints;
- dizziness;
- back pain;
- trouble sleeping;
- bone pain;
- fainting;
- change in or loss of taste;
- ear pain;
- ringing or buzzing in your ears;
- spinning sensation;
- coughing;
- sore throat;
- indigestion
- problems with your gums or the insides of your cheeks;
- excessive sweating;
- skin reactions: redness, rash, itching;
- dehydration.

Tell your doctor or nurse as soon as possible if you notice any of the following:

- frequent infections such as fever, severe chills, sore throat or mouth ulcers (symptoms of a lack of white blood cells);
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale (symptoms of a decreased number of red blood cells);
- bleeding or bruising more easily than normal (symptoms of a low blood platelet count);
- sore mouth, tongue, gums or toothache;
- mouth ulcers and cold sores;
- stomach pain;
- viral, bacterial or fungal infections;
- numbness or weakness of the arms and legs;
- severe stabbing or throbbing pain along the nerves;
- high blood pressure;
- low blood pressure;
- persistent constipation with a swollen stomach and vomiting;

- difficulty swallowing;
- painful swallowing;
- an allergic reaction;
- difficulties with body movement;
- loss of sense of touch;
- changes in your vision;
- dry eye.

These may be serious side effects. You may need medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- difficulty breathing, short of breath;
- chest pain;
- palpitations, fast or irregular heart beat;
- rash, itching or hives on the skin;
- swelling of the feet and ankles, face, lips, tongue or other parts of the body.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may occur in some patients. Tell your doctor, nurse or pharmacist 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.

After treatment with Javlor

Storage

Javlor Concentrated Injection vials are usually stored in the doctor's surgery or clinic, or at the pharmacy. However if you need to store Javlor:

Store the Javlor vials in the refrigerator (2 to 8°C). Do not freeze it. Protect Javlor from light.

Transport the Javlor vials refrigerated (2 to 8°C) protected from light in its original packaging.

Keep it where children cannot reach it.

Keep the Javlor vials in the original pack/container until it is time for it to be given.

Do not store Javlor or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness will destroy the medicine.

Disposal

If your doctor stops your treatment with Javlor, or it has passed its expiry date, return any left over vials to your pharmacist. Do not dispose of Javlor via wastewater or household waste. This will help to protect the environment.

Product description

What it looks like

Javlor is a concentrated clear, colourless to pale yellow solution containing 25 mg vinflunine per mL. It comes in a clear glass vial closed with a rubber stopper and sealed with an aluminium seal.

Javlor is available in 50 mg/2 mL, 100 mg/4 mL* and 250 mg/10 mL single use vials. It is supplied in packs of 1 and 10 vials.

Ingredients

Active ingredient:

- vinflunine ditartrate

Other ingredient:

- water for injections

Javlor is supplied by:
**Pierre Fabre Médicament
 Australia Pty Ltd**
 Suite 3B,
 1 Richardson Place
 North Ryde NSW 2113
 Australia

Australian Registration Number:

50 mg/2 mL: AUST R 166767

100 mg/4 mL*: AUST R 166772

250 mg/10 mL: AUST R 166773

* Not marketed

This leaflet was prepared in February 2011.