Fosaprepitant-AFT

Fosaprepitant dimeglumine

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Fosaprepitant-AFT?

Fosaprepitant-AFT contains the active ingredient Fosaprepitant dimeglumine. Fosaprepitant-AFT in combination with other medicines, is used to prevent nausea (feeling sick) and vomiting associated with cancer chemotherapy.

For more information, see Section 1. Why am I using Fosaprepitant-AFT? in the full CMI.

2. What should I know before i use Fosaprepitant-AFT?

Do not use if you have ever had an allergic reaction to Fosaprepitant dimeglumine or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Fosaprepitant-AFT? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Fosaprepitant-AFT and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Fosaprepitant-AFT?

Fosaprepitant-AFT 150 mg may be given to you as an infusion over 20-30 minutes approximately 30 minutes before you start your chemotherapy treatment.

More instructions can be found in Section 4. How do I use Fosaprepitant-AFT? in the full CMI.

5. What should I know while using Fosaprepitant-AFT?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using Fosaprepitant-AFT. Women taking oral contraceptive pills for birth control should also use other methods of contraception during treatment with Fosaprepitant-AFT and for one month following the last dose of Fosaprepitant-AFT. This is because oral contraceptive pills may not work as well when using Fosaprepitant-AFT If you become pregnant while using Fosaprepitant-AFT, tell your doctor immediately.
Driving or using machines	Fosaprepitant-AFT generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many medicines, it may cause certain side effects in some people, including tiredness and dizziness. Make sure you know how you react to Fosaprepitant-AFT before you drive a car or operate machinery.

For more information, see Section 5. What should I know while using Fosaprepitant-AFT? in the full CMI.

6. Are there any side effects?

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side effects?</u> in the full CMI.

Fosaprepitant-AFT

Active ingredient(s): Fosaprepitant dimeglumine

Consumer Medicine Information (CMI)

This leaflet provides important information about using Fosaprepitant-AFT. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Fosaprepitant-AFT.

Where to find information in this leaflet:

- 1. Why am I using Fosaprepitant-AFT?
- 2. What should I know before I use Fosaprepitant-AFT?
- 3. What if I am taking other medicines?
- 4. How do I use Fosaprepitant-AFT?
- 5. What should I know while using Fosaprepitant-AFT?
- 6. Are there any side effects?
- 7. Product details

Why am I using Fosaprepitant-AFT?

Fosaprepitant-AFT contains the active ingredient
Fosaprepitant dimeglumine. Fosaprepitant-AFT is an
antiemetic drug for prevention of chemotherapy induced
nausea and vomiting.

Fosaprepitant-AFT in combination with other medicines, is used to prevent nausea (feeling sick) and vomiting associated with cancer chemotherapy.

Fosaprepitant-AFT belongs to a group of medicines called neurokinin 1 (NK1) receptor antagonists. It works by blocking the actions of substances in your brain, called substance P neurokinins, that cause nausea and vomiting.

Your doctor may have prescribed Fosaprepitant-AFT for another reason. Ask your doctor if you have any questions about why Fosaprepitant-AFT has been prescribed for you.

The safety and effectiveness of Fosaprepitant-AFT in children and teenagers under the age of 18 years have not been established.

Fosaprepitant-AFT is not addictive.

2. What should I know before I use Fosaprepitant-AFT?

Warnings

Do not use Fosaprepitant-AFT if you:

- Are allergic to fosaprepitant, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- Are taking the medicines listed below. Using Fosaprepitant-AFT with these medicines may cause serious or life threatening reactions.
 - Cisapride, used to treat stomach reflux

- Pimozide, used to treat psychotic conditions
- Terfenadine and astemizole antihistamines used for allergic conditions, including hayfever
- St John's Wort a herb used to treat depression
- Are breast-feeding or plan to breastfeed. It is not known if Fosaprepitant-AFT passes into breast milk. You and your doctor should discuss whether you should stop breast-feeding or not be given Fosaprepitant-AFT.

Check with your doctor if you:

- Have any other medical conditions
- Take any medicines for any other condition
- Are pregnant or intend to become pregnant.
- Have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell them before you are given any Fosaprepitant-AFT.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Fosaprepitant-AFT has not been studied in pregnant women. Fosaprepitant-AFT should be used during pregnancy only if clearly needed.

3. What if I am taking other medicines?

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

Some medicines may interfere with Fosaprepitant-AFT and affect how it works.

Fosaprepitant-AFT should not be taken with the following medicines:

- Cisapride, used to treat stomach reflux
- Pimozide, used to treat psychotic conditions
- Terfenadine and astemizole antihistamines used for allergic conditions, including hayfever
- St John's Wort a herb used to treat depression

Using Fosaprepitant-AFT with these medicines may cause serious or life threatening reactions.

Some medicines and Fosaprepitant-AFT may interfere with each other. These include:

- Warfarin, used to prevent blood clots. Your doctor may order additional blood tests to check the effect of warfarin after you have been given Fosaprepitant-AFT
- Rifampicin, an antibiotic used to treat tuberculosis and other infections
- Ketoconazole, used to treat fungal infections
- Oral contraceptive pills (also known as the pill)
 Alternative or "back-up" measures of contraception should be used during treatment with Fosaprepitant-AFT and for one month following the last dose of Fosaprepitant-AFT
- Paroxetine, used to treat depression, and obsessive compulsive and panic disorders
- Diltiazem, used to treat angina and high blood pressure
- Midazolam, triazolam, or alprazolam, used as sedatives or to treat anxiety or panic disorder
- Dexamethasone or methylprednisolone, steroid medicines used for a variety of conditions
- Certain cancer chemotherapy agents, including etoposide, vinorelbine, paclitaxel
- Tolbutamide, used to treat diabetes
- Phenytoin, used to treat epilepsy

These medicines may be affected by Fosaprepitant-AFT or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using Fosaprepitant-AFT.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Fosaprepitant-AFT.

4. How do I use Fosaprepitant-AFT?

How much to take / use

Fosaprepitant-AFT is to be given intravenously.

Fosaprepitant-AFT must only be administered by your doctor or nurse.

Day 1 (Day of chemotherapy)

Fosaprepitant-AFT 150 mg may be given to you as an infusion over 20-30 minutes approximately 30 minutes before you start your chemotherapy treatment.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

When to take / use Fosaprepitant-AFT

Fosaprepitant-AFT is used for treatment of chemotherapy Induced nausea and vomiting. It should be is given only on the day of chemotherapy.

If you use too much Fosaprepitant-AFT

If you think that you have been given too much Fosaprepitant-AFT, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Fosaprepitant-AFT?

Things you should do

Women taking oral contraceptive pills for birth control should also use other methods of contraception during treatment with Fosaprepitant-AFT and for one month following the last dose of Fosaprepitant-AFT. This is because oral contraceptive pills may not work as well when using Fosaprepitant-AFT.

If you become pregnant while using Fosaprepitant-AFT, tell your doctor immediately.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using Fosaprepitant-AFT.

Things that may be helpful to manage your chemotherapy induced nausea and vomiting

Small, frequent meals or eating a snack before your chemotherapy treatment may help you to tolerate it better.

Talk to your doctor, pharmacist or nurse for more information.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Fosaprepitant-AFT affects you.

Fosaprepitant-AFT generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many medicines, it may cause certain side effects in some people, including tiredness and dizziness. Make sure you know how you react to Fosaprepitant-AFT before you drive a car or operate machinery.

Looking after your medicine

Fosaprepitant-AFT will be stored in the pharmacy or on the ward. The powder for injection is refrigerated at temperature of 2°C-8°C.

Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Stomach or bowel related Constipation Diarrhoea Indigestion Heartburn Loss of appetite Gas from the stomach or bowel Vomiting Bloating	Speak to your doctor if you have any of these less serious side effects and they worry you.
Body as a whole Tiredness General feeling of being unwell Muscle weakness Headache Dizziness Hiccups/hiccoughs Disorientation Chills Acne Pain on urination Hot flushes Changes to you walking pattern Injection site related Injection site pain Hardening at the injection site Redness and/or itching at the infusion site	

Serious side effects

Serious side effects	What to do
Blood and heart related Sign of anaemia such as being short of breath when exercising or looking pain Slow, fast or irregular heart beat	Call your doctor straight away, or go straight to the Emergency Department at your nearest

Serious decrease of blood pressure

Allergy related

- Symptoms of severe sunburn, such as redness, itching, pain, swelling or blistering
- Pinkish, itchy swellings on the skin, also called hives or nettle rash
- Swelling of the face, lips, mouth, throat or tongue which may cause difficulty in breathing or swallowing
- Severe skin reactions, including the inside of the nose or mouth
- Infusion site reactions (ISR) at or near the infusion site. These reactions have happened with Fosaprepitant-AFT. Most severe ISR have happened with a certain type of chemotherapy medicine that can burn or blister your skin (vesicant) with side effects, including pain, swelling and redness. Death of skin tissue (necrosis) has happened in some people getting this type of chemotherapy medicine.

Body as a whole:

- Frequent signs of infections such as fever, severe chills, sore throat or mouth ulcers
- Severe upper stomach pain

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side affects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

hospital if you notice any of these serious side effects.

What Fosaprepitant-AFT contains

Active ingredient (main ingredient)	Fosaprepitant dimeglumine
Other ingredients (inactive ingredients)	Lactose, Edetate disodium, Polysorbate 80, Sodium hydroxide, Hydrochloric acid

Do not take this medicine if you are allergic to any of these ingredients.

What Fosaprepitant-AFT looks like

Fosaprepitant-AFT is a white to off-white lyophilized powder (Aust R 378090).

Who distributes Fosaprepitant-AFT

AFT Pharmaceuticals Pty Ltd 113 Wicks Road North Ryde

NSW 2113

Australia

Email: customer.service@aftpharm.com This leaflet was prepared in July 2022