# **FOSAPREPITANT MSN**

# **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 MSN?

FOSAPREPITANT MSN contains the active ingredient fosaprepitant (as dimeglumine). FOSAPREPITANT MSN is used for chemotherapy induced nausea and vomiting.

For more information, see Section 1. Why am I using FOSAPREPITANT MSN? in the full CMI.

# 2. What should I know before I am given FOSAPREPITANT MSN?

Do not use if you have ever had an allergic reaction to fosaprepitant 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 am given FOSAPREPITANT MSN? in the full CMI.

## 3. What if I am taking other medicines?

Some medicines may interfere with FOSAPREPITANT MSN 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 is FOSAPREPITANT MSN given?

- FOSAPREPITANT MSN is to be given intravenously by your doctor and it contains 150 mg of fosaprepitant as the active ingredient.
- FOSAPREPITANT MSN must only be administered by your doctor or nurse.

More instructions can be found in Section 4. How is FOSAPREPITANT MSN given? in the full CMI.

## 5. What should I know while using FOSAPREPITANT MSN?

Things you should do	<ul> <li>Remind any doctor, dentist or pharmacist you visit that you are using FOSAPREPITANT MSN.</li> <li>Women taking oral contraceptive pills for birth control should also use other methods of contraception during treatment with FOSAPREPITANT MSN and for one month following the last dose of FOSAPREPITANT MSN.</li> </ul>
Driving or using machines	<ul> <li>Be careful driving or operating machinery until you know how FOSAPREPITANT MSN affects you.</li> <li>FOSAPREPITANT MSN generally does not cause any problems with your ability to drive a car or operate machinery.</li> </ul>
Storage	<ul> <li>FOSAPREPITANT MSN will be stored in the pharmacy or on the ward in the hospital.</li> <li>It is kept in a refrigerator where the temperature stays between 2-8°C.</li> </ul>

For more information, see Section 5. What should I know while using FOSAPREPITANT MSN? in the full CMI.

### 6. Are there any side effects?

FOSAPREPITANT MSN helps most people with nausea and vomiting associated with cancer chemotherapy, but it may have unwanted side effects in a few people. 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.

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

# **FOSAPREPITANT MSN**

**Active ingredient(s):** Fosaprepitant (as dimeglumine)

# **Consumer Medicine Information (CMI)**

This leaflet provides important information about using FOSAPREPITANT MSN. 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 MSN.

#### Where to find information in this leaflet:

- 1. Why am I using FOSAPREPITANT MSN?
- 2. What should I know before I am given FOSAPREPITANT MSN?
- 3. What if I am taking other medicines?
- 4. How is FOSAPREPITANT MSN given?
- 5. What should I know while using FOSAPREPITANT MSN?
- 6. Are there any side effects?
- 7. Product details

## Why am I using FOSAPREPITANT MSN?

# FOSAPREPITANT MSN contains the active ingredient fosaprepitant dimeglumine.

FOSAPREPITANT MSN 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.

FOSAPREPITANT MSN, in combination with other medicines, is used to prevent:

• nausea (feeling sick) and vomiting associated with cancer chemotherapy.

Your doctor may have prescribed FOSAPREPITANT MSN for another reason. Ask your doctor if you have any questions about why FOSAPREPITANT MSN has been prescribed for you

FOSAPREPITANT MSN is not addictive.

# 2. What should I know before I am given FOSAPREPITANT MSN?

#### Warnings

#### Do not use FOSAPREPITANT MSN if:

- you are allergic to fosaprepitant, aprepitant or any of the ingredients listed at the end of this leaflet.
   Always check the ingredients to make sure you can use this medicine.
- you are taking:
  - Cisapride, used to treat stomach reflux
  - Primozide, used to treat psychotic conditions

- Terfenadine (Teldane#) and astemizole (Hismanal#), antihistamines used for allergic conditions, including hayfever # not available in Australia
- St John's Wort a herb used to treat depression

Using FOSAPREPITANT MSN with these medicines may cause serious or life-threatening reactions.

If you are not sure whether you should start using FOSAPREPITANT MSN, talk to your doctor.

### Check with your doctor if you:

- have or have had any other medical conditions
- take any medicines for any other condition
- you have any allergies to any other medicines or any other substances, such as foods, preservatives, or dyes.

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 6. Are there any side effects?

### Pregnancy and breastfeeding

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

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

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

# Do not use FOSAPREPITANT MSN if you are breast-feeding or plan to breast feed.

It is not known if fosaprepitant passes into breast milk. You and your doctor should discuss whether you should stop breast-feeding or not be given FOSAPREPITANT MSN.

### Children

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

## 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 should not be taken with FOSAPREPITANT MSN. These include:

- Cisapride, used to treat stomach reflux
- Primozide, used to treat psychotic conditions

- Terfenadine (Teldane#) and astemizole (Hismanal#), antihistamines used for allergic conditions, including hayfever
  - # not available in Australia
- St John's Wort a herb used to treat depression

Using FOSAPREPITANT MSN with these medicines may cause serious or life-threatening reactions.

# Some medicines may interfere with FOSAPREPITANT MSN and affect how it works. 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 MSN.
- 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 MSN and for one month following the last dose of FOSAPREPITANT MSN
- Paroxetine, used to treat depression, and obsessive compulsive and panic disorders
- Diltiazem, used to treat angina and high blood pressure
- Midazolam, trizolam 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 MSN or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

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 MSN.

### 4. How is FOSAPREPITANT MSN given?

### How much to be given

- FOSAPREPITANT MSN is to be given intravenously by your doctor and it contains 150 mg of fosaprepitant as the active ingredient.
- FOSAPREPITANT MSN must only be administered by your doctor or nurse.

Day 1 (Day of chemotherapy) – FOSAPREPITANT MSN 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 use FOSAPREPITANT MSN

 FOSAPREPITANT MSN is given only on the day of chemotherapy.

# 5. What should I know while using FOSAPREPITANT MSN?

# Things you should do

 Women taking oral contraceptive pills for birth control should also use other methods of contraception during treatment with FOSAPREPITANT MSN and for one month following the last dose of FOSAPREPITANT MSN.

This is because oral contraceptive pills may not work as well when using FOSAPREPITANT MSN.

#### Call your doctor straight away if you:

- become pregnant while using FOSAPREPITANT MSN.
- are about to be started on any new medicine.

Remind any doctor, dentist or pharmacist you visit that you are using FOSAPREPITANT MSN.

# 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 MSN affects you.

FOSAPREPITANT MSN 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 MSN before you drive a car or operate machinery.

### Looking after your medicine

FOSAPREPITANT MSN will be stored in the pharmacy or on the ward in the hospital.

It is kept in a refrigerator where the temperature stays between 2-8°C.

# 6. 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
<ul> <li>tiredness</li> <li>generally feeling unwell</li> <li>muscle weakness</li> <li>headache, dizziness</li> <li>constipation, diarrhoea</li> <li>indigestion, heartburn, loss of appetite</li> <li>gas from the stomach or bowel, wind</li> <li>hiccups/hiccoughs</li> <li>vomiting</li> <li>disorientation</li> <li>chills</li> <li>hot flushes</li> <li>bloating</li> <li>pain on urination</li> <li>changes to your walking pattern</li> <li>acne</li> <li>injection site pain</li> <li>hardening at the injection site</li> <li>redness and/or itching at infusion</li> </ul>	Speak to your doctor if you have any of these less serious side effects and they worry you.

### Serious side effects

Serious side effects	What to do
<ul> <li>slow, fast or irregular heart beat</li> <li>severe upper stomach pain</li> <li>symptoms of severe sunburn, such as redness, itching, pain, swelling or blistering</li> <li>signs of anaemia such as, being short of breath when exercising, looking pale</li> <li>frequent signs of infection such as fever, severe chills, sore throat or mouth ulcers</li> <li>infusion site reactions (ISR) at or near the infusion site. These reactions have happened with fosaprepitant. Most severe ISR have happened with 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.</li> </ul>	Call your doctor straight away if you notice any of these serious side effects.

Very serious side effects	What to do
<ul> <li>swelling of the face, lips, mouth, throat or tongue which may cause difficulty in breathing or swallowing</li> <li>pinkish, itchy swellings on the skin, also called hives or nettlerash</li> <li>severe skin reactions, including the inside of the nose or mouth</li> <li>serious decrease of blood pressure.</li> <li>If you have these side effects, you may be having a serious allergic reaction to FOSAPREPITANT MSN.</li> <li>You may need urgent medical attention.</li> </ul>	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

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 effects you experience, you can report side effects to the Therapeutic Goods Administration online at <a href="https://www.tga.gov.au/reporting-problems">www.tga.gov.au/reporting-problems</a>. 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.

### What FOSAPREPITANT MSN contains

Active ingredient (main ingredient)	Each vial of FOSAPREPITANT MSN contains fosaprepitant dimeglumine equivalent to 150 mg of fosaprepitant free acid.
Other ingredients	disodium edetate
(inactive ingredients)	• polysorbate 80
	• lactose
	sodium hydroxide and hydrochloric acid

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

### What FOSAPREPITANT MSN looks like

FOSAPREPITANT MSN is available as a white to off-white powder in a single dose glass vial. (Aust R 372680).

# Who distributes FOSAPREPITANT MSN

Reach Pharmaceuticals Pty Ltd Ground Floor, Corporate One 84 Hotham Rd, Preston VIC 3072 medical@reach-pharma.com

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