# **Consumer Medicine Information (CMI) summary**

The <u>full CMI</u> 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 Aprepitant ARX?

Aprepitant ARX contains the active ingredient aprepitant. Aprepitant ARX, in combination with other medicines, is used to prevent nausea (feeling sick) and vomiting associated with cancer chemotherapy. Aprepitant ARX is used to prevent nausea (feeling sick) and vomiting which can occur after surgery.

For more information, see Section <u>1</u>. Why am I using Aprepitant ARX? in the full CMI.

### 2. What should I know before I use Aprepitant ARX?

Do not use if you have ever had an allergic reaction to aprepitant 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 Aprepitant ARX? in the full CMI.

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

Some medicines may interfere with Aprepitant ARX 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 Aprepitant ARX?

- Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.
- If you do not understand the instructions on the box, ask your doctor for help.
- Take this medicine only when prescribed by your doctor.

More instructions can be found in Section 4. How do I use Aprepitant ARX? in the full CMI.

#### 5. What should I know while using Aprepitant ARX?

Things you should do	<ul> <li>Remind any doctor, dentist, nurse, or pharmacist you visit that you are using Aprepitant ARX.</li> <li>Women taking oral contraceptive pills for birth control should also use other methods of contraception during treatment with this medicine and for one month following the last dose of this medicine.</li> <li>If you become pregnant while taking this medicine, tell your doctor immediately.</li> <li>If you are about to start on any new medicine, remind your doctor, nurse and pharmacist that you are taking this medicine.</li> <li>If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.</li> </ul>
Things you should not do	<ul> <li>Do not take this medicine to treat any other complaints unless your doctor tells you to.</li> <li>Do not give your medicine to anyone else, even if they have the same condition as you.</li> </ul>
Driving or using machines	<ul> <li>Be careful driving or operating machinery until you know how this medicine affects you.</li> <li>This medicine generally does not cause any problems with your ability to drive a car or operate machinery.</li> <li>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 this medicine before you drive a car or operate machinery.</li> </ul>
Looking after your medicine	<ul> <li>Keep your capsules in the pack until it is time to take them.</li> <li>Keep your medicine in a cool dry place where the temperature stays below 25°C.</li> <li>Do not store this medicine or any other medicine in the bathroom or near the sink. Do not leave it on a window sill or in the car.</li> <li>Keep this medicine out of the sight and reach of children.</li> </ul>

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

## 6. Are there any side effects?

Like all medicines, this medicine can cause side effects, although not everybody gets them. Your doctor will discuss these with you and will explain the risks and benefits of your treatment. Sometimes they may be serious, and you may require medical attention.

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.

# **Aprepitant ARX**

Active ingredient: Aprepitant

# **Consumer Medicine Information (CMI)**

This leaflet provides important information about using Aprepitant ARX. 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 Aprepitant ARX.

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

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

## 1. Why am I using Aprepitant ARX?

**Aprepitant ARX contains the active ingredient aprepitant.** Aprepitant ARX 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.

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

Aprepitant is used to prevent nausea (feeling sick) and vomiting which can occur after surgery.

## 2. What should I know before I use Aprepitant ARX?

#### Warnings

#### Do not use Aprepitant ARX if:

- you are allergic to 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.

#### Do not take this medicine if you are taking:

- 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 Taking aprepitant with these medicines may cause serious or life-threatening reactions.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. • If it has expired or is damaged, return it to your pharmacist for disposal.

#### Check with your doctor if you:

- have a rare hereditary problem of fructose intolerance
- have glucose-galactose malabsorption
- have sucrose-isomaltase insufficiency
- take any medicines for any other condition

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

#### 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.

Aprepitant has not been studied in pregnant women. This medicine should be used during pregnancy only if clearly needed. Your doctor can discuss with you the risks and benefits involved.

#### 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 Aprepitant ARX and affect how it works.

These include:

- 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.

Taking Aprepitant ARX with these medicines may cause serious or life-threatening reactions.

Some medicines and this one 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 taken aprepitant.
- 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 this medicine

and for one month following the last dose of this medicine

- 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 and paclitaxel
- tolbutamide, used to treat diabetes
- phenytoin, used to treat epilepsy

These medicines may be affected by this medicine or may affect how well it works. You may need different amounts of your medicines, 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 Aprepitant ARX.

# 4. How do I use Aprepitant ARX?

#### How much to take

- Follow all directions given to you by your doctor carefully.
- Follow the instructions provided and use Aprepitant ARX until your doctor tells you to stop.
- For chemotherapy induced nausea and vomiting This medicine may be given to you in one of two ways: 1-Day Regimen
  - Day 1 (day of chemotherapy):

One 165 mg capsule of this medicine will be given to you to take by mouth 1 hour before you start your chemotherapy treatment on Day 1 only. OR

#### 3-Day Regimen

#### • Day 1 (day of chemotherapy):

Once 125 mg capsule will be given to you by mouth 1 hour before you start your chemotherapy treatment on **Day 1.** 

• Day 2 and Day 3 (the two days after chemotherapy):

Take one 80 mg capsule of this medicine each morning for the 2 days following your chemotherapy treatment.

• For Post-Operative Nausea and Vomiting Your doctor will give you one 40 mg capsule of this medicine 3 hours before your surgery.

#### When to take Aprepitant ARX

Aprepitant ARX should be used when prescribed by your doctor.

#### How to take Aprepitant ARX

- Swallow the capsules whole with a full glass of water.
- This medicine can be taken with or without food.
- Follow your doctor's instructions about eating or drinking before surgery.

#### How long to take it

- For chemotherapy induced nausea and vomiting, this medicine may be given in one of two ways.
- For the 1-Day regimen, a 165 mg capsule is given only on the day of chemotherapy treatment.
- The 3-Day regimen is usually taken for 3 days.
- For post-operative nausea and vomiting, this medicine is given as 1 dose before your surgery.
- If you are not sure how long to take this medicine, talk to your doctor.

#### If you forget to use Aprepitant ARX

If you forget to take your capsules, contact your doctor for instructions.

#### If you use too much Aprepitant ARX

If you think that you have used too much Aprepitant ARX, 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 Aprepitant ARX?

#### Things you should do

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

This is because oral contraceptive pills may not work as well when taking this medicine.

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

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

If you are about to start on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

# If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

Remind any doctor, dentist or pharmacist or health care professional you visit that you are using Aprepitant ARX.

#### Things you should not do

• Do not take this medicine to treat any other complaints unless your doctor tells you to.

#### Driving or using machines

# Be careful before you drive or use any machines or tools until you know how Aprepitant ARX affects you.

This medicine 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 this medicine before you drive a car or operate machinery.

#### **Drinking alcohol**

#### Tell your doctor if you drink alcohol.

#### Looking after your medicine

- Keep your capsules in the pack until it is time to take them.
- If you take the capsules out of the pack, they may not keep well.
- Keep your medicine in a cool dry place where the temperature stays below 25°C.
- Do not store this medicine 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 can destroy some medicines.
- Keep it where children cannot reach it.
- A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep it where young children cannot reach it.

#### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 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 or dizziness</li> <li>constipation or diarrhoea</li> <li>indigestion, heartburn or loss of appetite</li> </ul>	Speak to your doctor if you have any of these less serious side effects and they worry you.

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•	wind or gas from the stomach or	The list
	bowel	includes the
•	hiccups/hiccoughs	more common
•	vomiting	side effects of
٠	disorientation	your medicine.
•	chills	They are
•	hot flushes	usually mild
•	bloating	and short-lived.
٠	pain on urination	
•	changes to your walking pattern	
•	acne	

#### 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 infections such as fever, severe chills, sore throat or mouth ulcers</li> <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 nettle rash</li> <li>severe skin reactions, including the inside of the nose or mouth</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 <u>www.tga.gov.au/reporting-problems</u>. 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 Aprepitant ARX contains

Active ingredient	Aprepitant
(main ingredient)	
Other ingredients	• sucrose
(inactive ingredients)	<ul> <li>microcrystalline cellulose</li> </ul>
	hypromellose
	<ul> <li>poloxameinsert</li> </ul>
	• gelatin
	<ul> <li>titanium dioxide</li> </ul>
	<ul> <li>sodium lauryl sulfate</li> </ul>
	<ul> <li>iron oxide yellow (40 mg capsules)</li> </ul>
	<ul> <li>iron oxide red (125 mg capsules)</li> </ul>
	<ul> <li>indigo carmine aluminium</li> <li>lake (165 mg capsules)</li> </ul>
	The capsules are printed with OPACODE monogramming ink S-1-17823 BLACK.
Potential allergens	phenylalanine
	• sulfites

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

#### What Aprepitant ARX looks like

Aprepitant ARX 165 mg capsules are presented as opaque hard gelatin capsules with a blue cap and white body, printed with "165mg" on the body. AUST R 309382.

Aprepitant ARX 125 mg capsules are presented as opaque hard gelatin capsules with a pink cap and white body, printed with "125mg" on the body. AUST R 309363.

Aprepitant ARX 80 mg capsules are presented as opaque hard gelatin capsules with a white cap and white body, printed with "80mg" on the body. AUST R 309361 and AUST R 309363.

Aprepitant ARX 40 mg capsules are presented as opaque hard gelatin capsules with a yellow cap and white body, printed with "40mg" on the body. AUST R 309345.

Available in blister packs containing:

1x 165 mg capsules

1x 125mg + 2x 80 mg capsules

2x 80mg capsule

1x 40mg capsule

\* Not all pack sizes may be available.

#### Who distributes Aprepitant ARX

This medicine is supplied in Australia by: Arrotex Pharmaceuticals Pty Ltd 15-17 Chapel Street Cremorne VIC 3121 www.arrotex.com.au

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