

# Nurtec<sup>®</sup> ODT

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## 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.

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▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

## 1. Why am I using Nurtec ODT?

Nurtec ODT contains the active ingredient rimegepant, that stops the activity of a substance in the body called calcitonin gene-related peptide (CGRP). People with migraine may have increased levels of CGRP. Nurtec ODT works by reducing the activity of CGRP in the body.

Nurtec ODT is used to treat and prevent migraine attacks, with or without aura, in adults.

For more information, see Section [1. Why am I using Nurtec ODT?](#) in the full CMI.

## **2. What should I know before I use Nurtec ODT?**

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

Talk to your doctor if you have any other medical conditions such as kidney or liver problems, take any other medicines, or are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed.

For more information, see Section [2. What should I know before I use Nurtec ODT?](#) in the full CMI.

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

Some medicines may interfere with Nurtec ODT 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 Nurtec ODT?**

- For treatment of a migraine attack, take one tablet, as needed, not more than once daily.
- For prevention of migraine, take one tablet every other day.
- Do not take more than one tablet (75 mg rimegepant) in a 24-hour period.

- Nurtec ODT can be taken with or without food or water. Use dry hands when opening the blister.

More instructions can be found in Section [4. How do I use Nurtec ODT?](#) in the full CMI.

## 5. What should I know while using Nurtec ODT?

<b>Things you should do</b>	<ul style="list-style-type: none"> <li>• Remind any doctor, dentist or pharmacist you visit that you are using Nurtec ODT.</li> <li>• If you intend to become pregnant and/or breastfeed while you are using Nurtec ODT, tell your doctor or pharmacist.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Migraines may cause drowsiness in some people. Caution is recommended if driving or using machines during a migraine attack, including after taking Nurtec ODT.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Store below 30°C and protect from moisture. Keep in original</li> </ul>

	<p>packaging until ready for use.</p> <ul style="list-style-type: none"> <li>• Keep it where young children cannot reach it.</li> </ul>
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For more information, see Section [5. What should I know while using](#) Nurtec ODT? in the full CMI.

## 6. Are there any side effects?

Speak to your doctor if you experience nausea and it worries you. Tell your doctor immediately and seek medical attention if you experience sudden signs of allergy such as skin rash, itching, shortness of breath, wheezing or coughing, swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing. These symptoms can occur several days after taking Nurtec ODT.

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.

- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/safety/reporting-problems](http://www.tga.gov.au/safety/reporting-problems).

## Nurtec<sup>®</sup> ODT

**Active ingredient(s):** *rimegepant*

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### Consumer Medicine Information (CMI)

This leaflet provides important information about using Nurtec ODT. **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 Nurtec ODT.**

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

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

## 1. Why am I using Nurtec ODT?

**Nurtec ODT contains the active ingredient rimegepant**, that stops the activity of a substance in the body called calcitonin gene-related peptide (CGRP). People with migraine may have increased levels of CGRP. Nurtec ODT works by reducing the activity of CGRP in the body and as a result:

1. it can stop an active migraine attack
2. it can decrease the number of migraine attacks that occur when taken prophylactically.

Nurtec ODT is used to treat and prevent migraine attacks, with or without aura, in adults.

## 2. What should I know before I use Nurtec ODT?

### Warnings

#### Do not use Nurtec ODT if:

- you are allergic to rimegepant, or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction may include:
  - shortness of breath
  - wheezing or difficulty breathing
  - swelling of the face, lips, tongue or other parts of the body
  - rash, itching or hives on the skin.

Always check the ingredients to make sure you can use this medicine.

## **Check with your doctor if you:**

- have or have had any other medical conditions, especially the following:
  - severe liver problems
  - reduced kidney function or are on kidney dialysis.
- take any medicines for any other condition
- have allergies to any other medicines, foods, preservatives or dyes.

If you have not told your doctor or pharmacist about any of the above, tell them before you start using Nurtec ODT.

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.

It is preferable to avoid taking Nurtec ODT during pregnancy as the effects of this medicine in pregnant women are not known.

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

Your doctor will discuss the possible risks and benefits of using Nurtec ODT during breastfeeding.

## **Children and adolescents**

Nurtec ODT should not be given to children and adolescents under 18 years of age. There is not enough information to recommend the use of this medicine in this age group.

### **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.

**The following is a list of examples of medicines that should be avoided when taking Nurtec ODT:**

- itraconazole and clarithromycin, medicines used to treat fungal or bacterial infections
- ritonavir and efavirenz, medicines used to treat HIV infections
- bosentan, a medicine used to treat high blood pressure
- St. John's wort, a herbal remedy used to treat depression
- phenobarbital, a medicine used to treat epilepsy
- rifampicin, a medicine used to treat tuberculosis
- modafinil, a medicine used to treat narcolepsy.



**Do not take Nurtec ODT more than once every 48 hours with:**

- fluconazole and erythromycin, medicines used to treat fungal or bacterial infections
- diltiazem, quinidine and verapamil, medicines used to treat an abnormal heart rhythm, chest pain (angina) or high blood pressure
- ciclosporin, a medicine used to prevent organ rejection after an organ transplant.

These medicines may be affected by Nurtec ODT or may affect how well it works. You may need different amounts of your medicine, or 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 Nurtec ODT.**

## **4. How do I use Nurtec ODT?**

### **How much to take**

- For treatment of a migraine attack once it has started, the recommended dose is one tablet (75 mg rimegepant) as needed, not more than once daily.
- For prevention of migraine, the recommended dose is one tablet (75 mg rimegepant) every other day.

Do not take more than one tablet (75 mg rimegepant) in a 24-hour period. This includes any tablet you may have taken to prevent an attack.

## How to take Nurtec ODT

Nurtec ODT is for oral use. Nurtec ODT can be taken with or without food or water.



1. Use dry hands when opening. Peel back the foil covering of one blister and gently remove the tablet. Do not push the tablet through the foil.



2. As soon as the blister is opened, remove the tablet and place it on or under the tongue, where it will dissolve. No drink or water is needed. Do not store the tablet outside the blister for future use.

## **If you forget to use Nurtec ODT**

If you take Nurtec ODT for the prevention of migraine and it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

**Do not take a double dose to make up for the dose you missed.**

## **If you use too much Nurtec ODT**

If you think that you have used too much Nurtec ODT, 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 Nurtec ODT?**

### **Things you should do**

**Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Nurtec ODT.**

**If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Nurtec ODT.**

**If you become pregnant while taking Nurtec ODT, tell your doctor.**

## **Things you should not do**

- Do not give Nurtec ODT to anyone else, even if they have the same condition as you.
- Do not take Nurtec ODT to treat any other complaints unless your doctor or pharmacist tells you to.
- Do not stop taking Nurtec ODT, or change the dosage, without checking with your doctor or pharmacist.

## **Driving or using machines**

Migraines may cause drowsiness in some people. Caution is recommended if driving or using machines during a migraine attack, including after taking Nurtec ODT.

## **Looking after your medicine**

- Store below 30°C. Protect from moisture.
- Keep in the original packaging until ready for use.

Do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Do not use this medicine after the expiry date which is stated on the carton and the blister.

**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.

## **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.

### **Common side effects**

<b>Common side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"><li>• nausea</li></ul>	<b>Speak to your doctor if you have any of these side effects and they worry you.</b>

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>• allergic reactions. Signs of an allergic reaction include<ul style="list-style-type: none"><li>◦ skin rash, itching</li><li>◦ shortness of breath, wheezing or coughing</li><li>◦ swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing</li></ul></li></ul> <p>This symptom can occur several days after taking Nurtec ODT.</p>	<p><b>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.</b></p> <p>You may need urgent medical attention. Serious side effects are rare.</p>

**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 [www.tga.gov.au/safety/reporting-problems](http://www.tga.gov.au/safety/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.

### **What Nurtec ODT contains**

<b>Active ingredient (main ingredient)</b>	rimegepant
<b>Other ingredients (inactive ingredients)</b>	gelatin* mannitol mint flavour sucralose

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

\*Gelatin is derived from fish.

### **What Nurtec ODT looks like**

Nurtec ODT tablets are white to off-white, circular, and debossed with the symbol consisting of two quadrants.

AUST R 392434

Available in blister packs of 2 or 8 orally disintegrating tablets.

## **Who distributes Nurtec ODT**

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229

[www.pfizermedicalinformation.com.au](http://www.pfizermedicalinformation.com.au)

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