Patient leaflet in accordance with the Pharmacists Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Nurtec ODT®

Orally disintegrating tablets

For oral or sublingual use

Active ingredient and quantity:
Each orally disintegrating tablet contains:
rimegepant 75 mg (equivalent to 85.65 mg rimegepant sulfate)

For a list of inactive ingredients and allergens in this medicine, see section 6 "Further information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine.
If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Nurtec ODT, orally disintegrating tablets, are indicated for:
- Acute treatment of migraine attacks with or without aura in adults.
- Preventive treatment of episodic migraine.

Therapeutic group: Calcitonin gene-related peptide (CGRP) receptor antagonist, antimigraine medicine.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient (rimegepant) or to any of the other ingredients in this medicine (see section 6).

Special warnings regarding use of the medicine

Allergic reactions. Allergic reactions, including trouble breathing and rash, can happen after you take this medicine. This can happen days after you take the medicine. If you experience an allergic reaction, stop using it and begin appropriate treatment (see section 4 "Side effect").

Before treatment with Nurtec ODT, tell your doctor if:
- You have high blood pressure.
- You have circulation problems in your fingers and toes.
- You have liver problems.
- You have kidney problems.
- You are pregnant or plan to become pregnant.
- You are breastfeeding or plan to breastfeed.

Children and adolescents
There is no information regarding the safety and effectiveness of this medicine in children and adolescents.

Drug interactions
If you are taking or have recently taken, other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist.

- Avoid taking this medicine with CYP3A4 inhibitors such as itraconazole - for the treatment of fungal infections.
- Avoid taking this medicine with CYP3A inducers such as rifampicin - for the treatment of tuberculosis.
- Avoid taking this medicine with inhibitors of P-gp or BCRP such as amiodarone - for the treatment of arrhythmias.

Pregnancy, breastfeeding, and fertility
Pregnancy
There is no information about the developmental risk associated with the use of this medicine in pregnant women.
Breastfeeding
Very small amounts of Nurtec ODT pass into your breast milk. Talk with your doctor about the best way to feed your baby if you take Nurtec ODT.

3. HOW TO USE THIS MEDICINE?

Always use this medicine according to your doctor's instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the medicine.
The dosage and treatment regimen will be determined by your doctor only. **The standard dosage is usually:**

- For the acute treatment of migraine attacks when they occur, Nurtec ODT can be taken once a day, as required. You should not take more than 1 tablet in 24 hours.
- It is not known if it is safe to take more than 18 doses of Nurtec ODT in 30 days.
- For the preventive treatment of episodic migraine, take Nurtec ODT 1 time every other day.

Do not exceed the recommended dose.

How to use

- Your hands should be dry when opening the blister pack.
- Peel back the foil covering of one blister and gently remove a single tablet. Do not push the tablet through the foil.
- As soon as the blister is opened, remove the tablet and place on or under the tongue.
- The tablet will dissolve, and no drink or water is needed.
- Take the tablet immediately after opening the blister pack.
- Do not store the medicine outside the blister pack for future use.

If you have accidentally taken a higher dosage
If you have taken an overdose, or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

Adhere to the treatment as recommended by your doctor.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Nurtec ODT orally disintegrating tablets, may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

The medicine may cause serious side effects, including:

- **Allergic reactions.** Allergic reactions, including trouble breathing and rash, can happen after you take this medicine. This can happen days after you take the medicine.
- **High blood pressure**. High blood pressure or worsening of high blood pressure can happen after you take NURTEC ODT. Contact your doctor if you have an increase in blood pressure.
- **Raynaud's phenomenon.** A type of circulation problem that can worsen or happen after you take NURTEC ODT. Raynaud's phenomenon can lead to your fingers or toes feeling numb, cool, or painful, or changing color from pale to blue to red. Contact your doctor if these symptoms occur.

Contact your doctor immediately or get emergency medical treatment if you have any of the following symptoms, which may be part of an allergic reaction:

- Swelling of the face, mouth, tongue or throat
- Trouble breathing
- Rash

The most common side effect of the medicine in acute treatment of migraine attacks with or without aura is:

- Nausea

The most common side effects of the medicine in preventive treatment of episodic migraine are:

- nausea
- stomach pain
- indigestion

There may be additional side effects.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link: https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?

- Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store the medicine in the blister package that it comes in.
- Store the medicine below 25˚C. Store in the original package in order to protect from moisture.
- Do not throw away the medicine via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:
benzyl alcohol, eucalyptol, gelatin, limonene, mannitol, menthol, menthone, menthyl acetate, sucralose micronized, and vanillin.

What the medicine looks like and contents of the pack:
White to off-white, round tablets debossed with the symbol
The medicine is marketed in a carton containing a blister pack of 2 or 8 tablets.
Not all pack sizes may be marketed.

Registration holder and address:
Pfizer Pharmaceuticals Israel Ltd.,
9 Shenkar St., Herzliya Pituach 46725.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
166-81-36535-99

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