Orzeyful™
oveporexton tablets (IV)



Actor portrayal.

GETTING STARTED

on your new treatment for narcolepsy type 1 (narcolepsy with cataplexy)

Use this guide to help you get started taking ORZEYFUL™.

What is ORZEYFUL?

ORZEYFUL™ is a prescription medicine used in adults to treat narcolepsy type 1 (narcolepsy with cataplexy).

It is not known if ORZEYFUL is safe and effective in children under 18 years of age.

IMPORTANT SAFETY INFORMATION

Do not take ORZEYFUL if you take certain medicines that are strong inhibitors of an enzyme called CYP3A, since they may increase your risk of side effects. Ask your healthcare provider if you are not sure.

Please see additional Important Safety Information throughout and click for full Prescribing Information and talk with your healthcare provider.

ORZEYFUL was studied in 2 different 12-week clinical studies that included a total of 273 people with narcolepsy type 1 (NT1).

In both studies, ORZEYFUL was taken twice daily and compared with placebo (sugar pill). The main goal of these studies was to evaluate wakefulness, along with the other main symptoms of NT1.

Study 1:
168 people took ORZEYFUL (1 mg or 2 mg) or placebo for 12 weeks

Study 2:
105 people took ORZEYFUL (2 mg) or placebo for 12 weeks

People taking ORZEYFUL saw improvement across the full range of narcolepsy type 1 symptoms



Wakefulness



Cataplexy



Daytime sleepiness



Overall symptom severity and change

Explore the clinical study results at **orzeyful.com**

IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of ORZEYFUL?

- **ORZEYFUL may cause serious side effects, including:**
  - **Trouble sleeping (insomnia).** Tell your healthcare provider if you develop insomnia, especially if it does not go away after 7 days, while taking ORZEYFUL. They may decrease your dose or tell you to stop taking ORZEYFUL.

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What are the most common side effects of ORZEYFUL?

- Trouble sleeping (insomnia)
- Urinary urgency
- Increased urinary frequency
- Increased saliva

These are not all of the possible side effects of ORZEYFUL. For more information, ask your healthcare provider or pharmacist.

Trouble sleeping

In the 12-week clinical studies, 58% of people taking ORZEYFUL experienced trouble sleeping (insomnia). Approximately 94% of insomnia events started within the first 7 days of taking ORZEYFUL. Approximately 63% of insomnia events resolved within 1 week after insomnia first started and approximately 17% of insomnia events were ongoing at the end of 12 weeks.

Urinary side effects

In the 12-week clinical studies, 63% of people taking ORZEYFUL experienced urinary side effects.

Two people treated with ORZEYFUL stopped treatment due to urinary side effects.

IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of ORZEYFUL? (cont'd)

- **ORZEYFUL may cause serious side effects, including: (cont'd)**
  - **Urinary frequency and urgency.** Tell your healthcare provider if you urinate more often or have sudden urges to urinate. If you have a history of overactive bladder, your healthcare provider may monitor you for worsening urinary symptoms.
  - **Increased level of an enzyme in your blood called creatine phosphokinase (CPK).** Increased CPK may be a sign of muscle damage. Tell your healthcare provider right away if you have unexplained muscle pain, weakness, or dark urine, especially after vigorous physical activity, or if you take other medicines that may cause muscle problems.

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Only ORZEYFUL targets the underlying loss of orexin in NT1 by activating orexin receptors in the brain to restore orexin signaling.

How ORZEYFUL works in NT1

Orexin receptor 2 (activated) · Orexin · Orexin receptor 2 (inactive) · ORZEYFUL

For illustrative purposes only.



Orexin attaches to important receptors in the brain that send signals to the rest of your body.

People with NT1 have a loss, or low levels, of orexin in the brain.

ORZEYFUL targets the underlying loss of orexin in NT1 by attaching to and activating orexin receptor 2 in the brain to restore orexin signaling.

IMPORTANT SAFETY INFORMATION (cont'd)

What are the possible side effects of ORZEYFUL? (cont'd)

- **Most common side effects of ORZEYFUL include** trouble sleeping (insomnia), increased urinary frequency, urinary urgency, and increased saliva.

  These are not all the possible side effects of ORZEYFUL. Call your healthcare provider for medical advice about side effects.

Please see additional Important Safety Information throughout and click for full Prescribing Information and talk with your healthcare provider.

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Taking ORZEYFUL: What you should know

How do I take ORZEYFUL?

- Be sure to take ORZEYFUL exactly how your healthcare provider tells you to take it
- Take ORZEYFUL at approximately the same time each day
- ORZEYFUL tablets should be swallowed whole with water. Do not split, crush, or chew tablets
- ORZEYFUL can be taken with or without food
- Do not drink grapefruit juice during ORZEYFUL treatment

One tablet
Twice daily

WITH OR WITHOUT FOOD

FIRST TABLET: after waking up

SECOND TABLET: 3 to 5 hours later

How does ORZEYFUL fit into your day?

- ORZEYFUL comes in 1 mg or 2 mg tablets that should be taken twice a day
- The first dose should be taken when you wake up, and the second dose, 3 to 5 hours later
- You should not take more than 4 mg within 24 hours

ⓘ If you take certain medicines, your healthcare provider may prescribe ORZEYFUL at a lower dose of 0.5 mg

If you accidentally miss a dose:

- Skip the missed dose and take the next dose at the next regular time
- Do not take 2 doses at the same time

If you take too much ORZEYFUL:

- Call your healthcare provider or go to the nearest hospital emergency room right away

IMPORTANT SAFETY INFORMATION (cont'd)

Before taking ORZEYFUL, tell your healthcare provider about all your medical conditions, including if you:

- have a history of overactive bladder
- have a history of drug or alcohol abuse or addiction
- have severe liver or kidney problems

Please see additional Important Safety Information throughout and click for full Prescribing Information and talk with your healthcare provider.

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Track your progress with ORZEYFUL

A new treatment routine can take some getting used to. It's helpful to capture your thoughts and experiences, and share them with your healthcare provider.

1. **What were your NT1 symptoms before taking ORZEYFUL?**

___ Trouble staying awake during the day

___ Cataplexy

___ Other _____

_____

2. **When did you start taking ORZEYFUL?**

_____

3. **Use the space below to write down the initial dose prescribed by your healthcare provider and any additional changes you and your healthcare provider made.**

Date _____ Dose _____ Date _____ Dose _____

IMPORTANT SAFETY INFORMATION (cont'd)

Before taking ORZEYFUL, tell your healthcare provider about all your medical conditions, including if you: (cont'd)

- are pregnant or plan to become pregnant. It is not known if ORZEYFUL will harm your unborn baby.
  - There is a pregnancy registry for women who are exposed to ORZEYFUL during pregnancy. The registry collects information about the health of you and your baby. To enroll or get information from the registry, call 1-877-371-0309.
- are breastfeeding or plan to breastfeed. Talk to your healthcare provider about the best way to feed your baby if you take ORZEYFUL.

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Notes to discuss with your healthcare provider

Talk with your healthcare provider about what you're experiencing so you can find a rhythm that works for you.

1. **Are you noticing improvements in your NT1 symptoms since taking ORZEYFUL?**
   (Check all that apply)

   ___ Decreased daytime sleepiness

   ___ Reduced cataplexy

   ___ Decreased overall NT1 symptom severity (excessive daytime sleepiness, cataplexy, sleep paralysis, hallucinations, and disrupted nighttime sleep)

2. **What is the biggest change you've noticed since taking ORZEYFUL?**
   (Please describe)

   _____

   _____

3. **Keep track of your daytime sleepiness score every 3 months by using the Epworth Sleepiness Scale (ESS) available by clicking here.**
   (Please write scores below)

   Date _____ Score _____ Date _____ Score _____

4. **Write down any questions you have about taking ORZEYFUL.**
   (Please describe)

   _____

   _____

   _____

   _____

IMPORTANT SAFETY INFORMATION (cont'd)

Tell your healthcare provider about all the medicines you take, including prescription medicines and over-the-counter medicines, vitamins, and herbal supplements. Some medicines may affect how ORZEYFUL works or increase your risk of side effects. Do not start, stop, or change any other medicine while taking ORZEYFUL without talking to your healthcare provider.

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Actor portrayal.

We're here to support you
with information during your ORZEYFUL treatment journey

Visit **MyORZEYFUL.com** for more information and to enroll in Takeda Patient Support.

IMPORTANT SAFETY INFORMATION (cont'd)

ORZEYFUL is a federally controlled substance (CIV) because it can be abused or lead to dependence. Tell your healthcare provider if you have ever abused or been dependent on alcohol, prescription medicines, or street drugs. Keep your ORZEYFUL in a safe place and never give it to anyone else.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see additional Important Safety Information throughout and click for full Prescribing Information and talk with your healthcare provider.

Takeda

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