

Package leaflet: Information for the patient

ZTALMY 50 mg/mL oral suspension ganaxolone

▼ 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 or the patient may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you or your child start taking this medicine because it contains important information.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours or your child's.
- If you get any side effects, talk to your doctor, or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What ZTALMY is and what it is used for
2. What you or your child need to know before taking ZTALMY
3. How to take ZTALMY
4. Possible side effects
5. How to store ZTALMY
6. Contents of the pack and other information

1. What ZTALMY is and what it is used for

ZTALMY contains the active substance ganaxolone, a neuroactive steroid that works by attaching to specific receptors and stops the brain from having epileptic seizures.

ZTALMY is used to treat a rare epileptic seizure disorder called 'cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder' (CDD) in patients 2 to 17 years of age. If ZTALMY is helping to treat your seizures, it can still continue to be used when you or your child turns 18.

ZTALMY is used in combination with other anti-epileptic medicines.

This medicine will reduce the number of daily epileptic seizures you or your child may experience.

2. What you or your child need to know before taking ZTALMY

Do not take ZTALMY if you are allergic to ganaxolone or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking ZTALMY if:

- **you or your child feel drowsy**
ZTALMY can cause drowsiness or sleepiness, or the feeling of being overly calm and relaxed (i.e. feeling sedated). Talk to your doctor or pharmacist before taking ZTALMY if you have any concerns about these effects or if you are taking central nervous system depressants such as other medicines to treat seizures, opioids, antidepressants or alcohol, as these can increase the sleepiness and sedative effects of ZTALMY.

- **you or your child have had thoughts about harming or killing yourself**
If you notice unusual changes in your mood or behaviour or have thoughts of harming or killing yourself, **contact your doctor straightaway.**
If you are caring for a child with CDD, look out for any unusual changes in their mood or behaviour or anything they say that could mean they are thinking about self-harming or killing themselves. **If you notice any of these, contact your doctor straightaway.**
- **you or your child have a history of alcohol or drug addiction**
ZTALMY has the potential to be abused or used for the wrong purpose. Talk to your doctor or pharmacist before taking ZTALMY if you have a medical history of alcohol or drug abuse.
- **you or your child have severe liver problems**
Your doctor will monitor you closely during treatment and may reduce your dose of ZTALMY.

Children and adolescents

ZTALMY must not be given to children under the age of 2 years since there is no information on use in children below this age.

Other medicines and ZTALMY

Tell your doctor or pharmacist if you or your child are taking, have recently taken or might take any other medicines. Taking ZTALMY with certain other medicines may cause side effects, affect how other medicines work or affect how ZTALMY works.

Do not start or stop taking other medicines without talking to your doctor or pharmacist first.

Tell your doctor if you or your child are taking any of the following medicines, as your dose of ZTALMY may need to be adjusted:

- Valproate-containing medicines, which are used to treat epilepsy, they may require your dose of ZTALMY to be lower;

Medicines that may reduce how ZTALMY works may require your dose of ZTALMY to be higher:
- Other antiepileptic or anticonvulsant medicines such as carbamazepine, phenytoin, phenobarbital and primidone;
- Antibiotics such as rifampicin;
- St. John's Wort (*Hypericum perforatum*), a herbal remedy used for mild depression.

The interaction between this medicine and oral contraceptives has not been investigated. Talk to your doctor if you are taking oral contraceptives.

ZTALMY with alcohol

Alcohol should not be consumed as it can increase the sleepiness and sedative effects of ZTALMY.

Pregnancy

If you are pregnant or think you may be pregnant, ask your doctor or pharmacist for advice before taking this medicine.

ZTALMY is not recommended if you are pregnant or a women of child-bearing potential and not using contraception.

Breast-feeding

Do not use ZTALMY whilst breast-feeding unless your doctor decides the benefits of taking ZTALMY outweighs any potential risks.

Driving and using machines

ZTALMY can make you feel drowsy/sleepy. If affected, do not drive, ride a bicycle or operate a machine until you feel more alert.

ZTALMY contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per each mL, that is to say, it is essentially 'sodium-free'.

ZTALMY contains sodium benzoate and benzoic acid

This medicine contains 0.92 mg sodium benzoate and 0.00068 mg benzoic acid in each mL. Sodium benzoate and benzoic acid may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

ZTALMY contains benzyl alcohol

This medicine contains 0.00023 mg benzyl alcohol in each mL. Benzyl alcohol may cause allergic reactions. Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called "gasping syndrome") in young children. Do not give to your newborn baby (up to 4 weeks old), unless recommended by your doctor. Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist. Increased risk due to accumulation in young children. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding, or if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called 'metabolic acidosis').

ZTALMY contains methyl parahydroxybenzoate and propyl parahydroxybenzoate

This medicinal product contains 1.02 mg methyl parahydroxybenzoate and 0.2 mg propyl parahydroxybenzoate in each mL which may cause allergic reactions (possibly delayed).

3. How to take ZTALMY

ZTALMY is given under supervision of a doctor experienced in the treatment of epilepsy. Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

It is an oral suspension (a liquid to be swallowed). Your doctor or pharmacist will tell you how much (in mL) of the oral suspension to take each day, and how many times a day you should take it.

Your doctor will calculate the dose according to your body weight. You may start on a low dose that your doctor gradually increases over time.

If you have severe hepatic impairment, your doctor will start you on a lower dose and follow a different titration schedule.

Patient weighing less than or equal to 28 kg

You or your child will gradually have your dose increased over 4 weeks until you receive the recommended maximum daily dose of 63 mg/kg/day given in three separate doses every 8 hours.

Patient weighing more than 28 kg

You or your child will gradually have your dose increased over 4 weeks until you receive the recommended maximum daily dose of 1 800 mg/day given in three separate doses every 8 hours.

It is recommended that you take 3 equal doses throughout the day. However, ZTALMY can make you feel sleepy, and your doctor may decide you should be given a lower dose during the daytime and a higher dose in the evening to avoid any sleepy effects during the daytime.

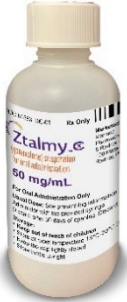
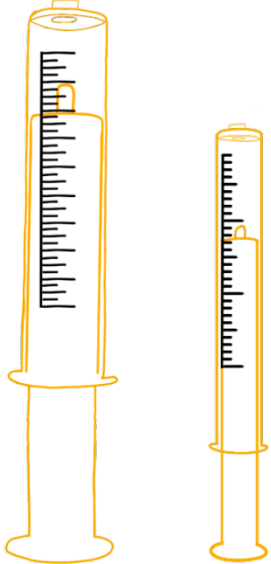

Talk to your doctor if you are unsure of your dose or if you think it may need to be changed.

How to take ZTALMY

- Take the medicine with or shortly after meals
- If possible, try to take with similar types of food (e.g. similar fat content) so you get the same effect each time
- Do not mix ZTALMY with food or drink
- To ensure an accurate dose, please use the reusable oral dosing syringes provided in each pack.

Instructions for use

Each single-bottle pack is supplied with:




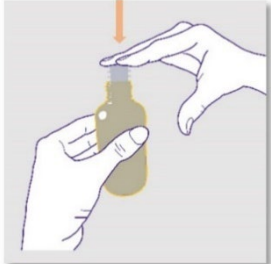
One bottle of oral suspension closed with a child resistant cap	
Two 12 mL and two 3 mL reusable oral dosing syringes	
One bottle adaptor	

ZTALMY is also supplied in a pack with five bottles of oral suspension, five 12 mL reusable oral dosing syringes and five bottle adaptors. Please note that the pack containing five bottles of ZTALMY does not include a 3 mL reusable oral dosing syringe.

- Ask your doctor, pharmacist or nurse if you are not sure how to prepare or take the prescribed dose of ZTALMY.
- You will receive 12 mL and 3 mL reusable oral dosing syringes in the single-bottle pack. If your dose is 3 mL or less, use the smaller 3 mL syringes to take your medicine. If your dose is more than 3 mL use the larger 12 mL syringes to take your dose.

- Always use the correct reusable oral dosing syringe provided with ZTALMY to make sure you measure the right amount of ZTALMY. Do not use a household spoon. Do not mix ZTALMY with food or drink to administer.
- Each 3 mL dosing syringe may be used for 16 consecutive days. After 16 days, throw away the used dosing syringe and use the spare syringe contained in the carton.
- Use ZTALMY within 30 days of first opening the bottle. There is space on the bottle label for you to write down the date for discarding the bottle after opening so you do not forget.
- After 30 days, discard any ZTALMY that has not been used, and use a new bottle.

Preparing the bottle:

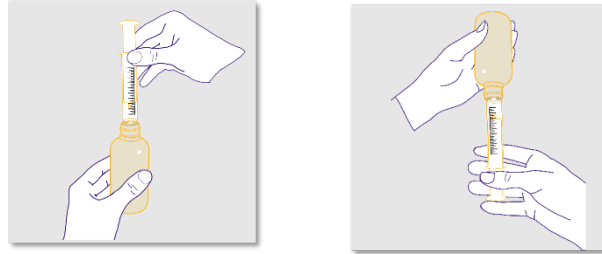
<p>1. Hold the bottle in your hand and shake it up and down well for 1 minute.</p> <p>Always shake the bottle well for 1 minute then let the bottle stand for 1 minute so that any foam that builds up during shaking can settle before measuring and giving each dose of ZTALMY. This helps you measure the correct amount of medicine.</p> <p>NOTE: This step is for each dose of the medicine.</p>	
<p>2. Remove the child-resistant cap on the bottle by pushing the cap down whilst turning the cap to the left (anti-clockwise).</p>	
<p>3. Puncture and peel off the induction seal from the bottle.</p> <p>NOTE: This step is only for the first use of the bottle.</p>	
<p>4. Hold the bottle tight with one hand while pushing the bottle adaptor firmly into the neck of the bottle with the other hand, and make sure it is fully inserted. The adaptor could come off and cause choking if it is not fully inserted.</p> <p>NOTE: Do not remove the press-in bottle adaptor from the bottle after it is inserted.</p>	

Preparing the dose:

5. Insert the tip of the correct reusable oral dosing syringe fully into the bottle adaptor, and with the oral syringe in place, turn the bottle upside down.

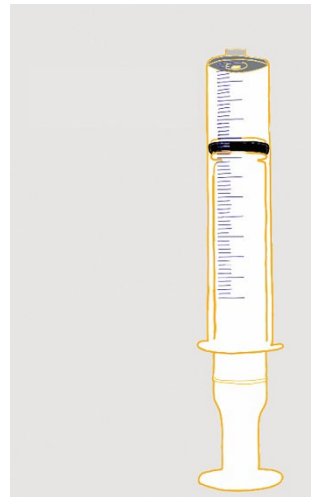
It is important that you use the correct reusable oral dosing syringe to measure your dose:

- If your dose is 3 mL (150 mg) or less, you should use the smaller 3 mL syringe.
- If your dose is more than 3 mL (150 mg), you should use the larger 12 mL syringe.

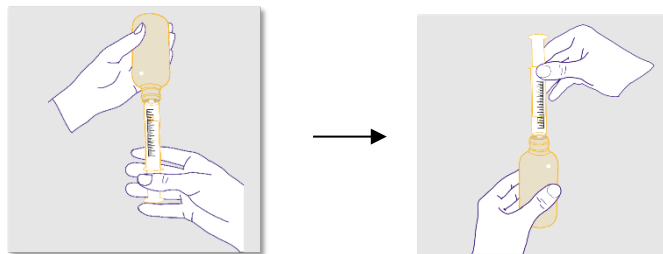


6. Slowly pull back the plunger of the syringe, so the volume (number of mL) of oral suspension needed is drawn into the syringe. Line up the end of the plunger with the volume marking required, as shown opposite.

If there is an air bubble in the syringe, push the liquid back into the bottle whilst keeping the bottle upside down, and repeat Step 6 until the bubble has gone.



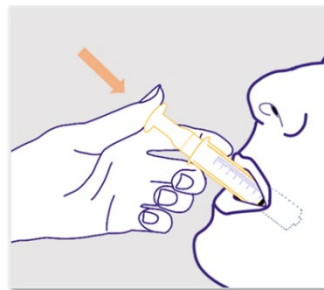
7. Turn the bottle the right side up, and carefully remove the oral syringe from the adaptor.



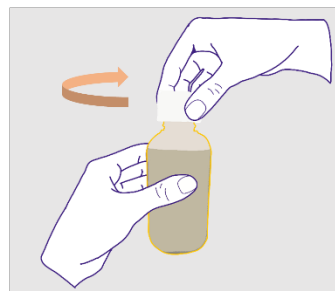


Taking or giving ZTALMY:

8. Place the tip of the oral syringe inside the cheek, and gently push the plunger to release the medicine. Do not push the plunger forcefully or direct the medicine to the back of the mouth or throat.

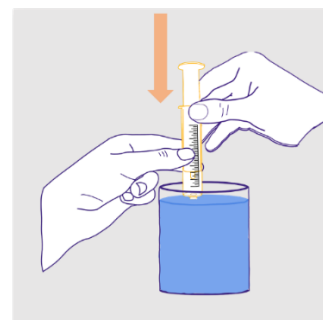


9. Screw the child resistant cap back on the bottle tightly, by turning the cap to the right (clockwise). You do not need to remove the bottle adaptor; the cap will fit over it.

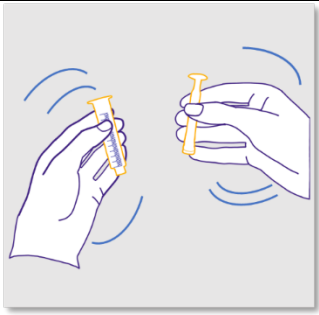


10. Wash the oral syringe immediately after use. Remove the plunger from the barrel of the syringe, and rinse both parts using room temperature tap water.

Warning:
Do not use bleach or any other harsh cleaning solutions.
Do not wash the oral syringe in a dishwasher.



11. Shake off any water from both syringe parts and allow them to air-dry separately until the next use. Make sure both parts are completely dry before placing the plunger back into the syringe barrel for the next

<p>use. If both parts are not completely dry before the next dose, use the appropriate spare syringe provided in the pack.</p> <p>When using the 12 mL syringe accompanying each bottle, do not throw away the reusable oral syringes until the bottle is empty. When using the 3 mL syringe, discard after 16 days.</p>	
<p>12. Repeat steps 1-3 and 6-12 for each next dose.</p>	

If you take more ZTALMY than you should

If you accidentally take more ZTALMY than you should, tell a doctor or pharmacist immediately, or contact your nearest hospital casualty department, and take the medicine with you. You may feel drowsy or sleepy from taking too much medicine.

If you forget to take ZTALMY

If you forget to take a dose, the missed dose may be taken up to 4 hours before the next scheduled dose. When the next dose is due in less than 4 hours, it is recommended to skip the dose and continue with the next scheduled dose.

If you stop taking ZTALMY

Do not reduce the dose or stop taking ZTALMY without first talking to your doctor. Stopping this treatment abruptly could increase your seizures. The doctor will explain how to gradually stop taking ZTALMY.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You may get the following side effects with this medicine. **Tell the doctor** if you have any of the following:

Very common (may affect more than 1 in 10 people):

- feeling drowsy or sleepy;
- fever.

Common (may affect more than 1 in 100 people):

- feeling overly calm or relaxed;
- feeling excessively tired during the day or sleeping longer than usual at night;
- lack of energy;
- drooling;
- producing more saliva than usual.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme. Website www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store ZTALMY

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the bottle label after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions. Discard any unused medicine 30 days after first opening.

Do not throw away any medicines in the wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What ZTALMY contains

- The active substance is ganaxolone. Each mL of oral suspension contains 50 mg of ganaxolone.
- The other ingredients are: hypromellose (E464), polyvinyl alcohol (E1203), sodium lauryl sulfate (E487), methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), sodium benzoate (E211), citric acid anhydrous (E330), sodium citrate dihydrate (E331), artificial cherry flavour (including propylene glycol [E1520] and benzyl alcohol [E1519]), sucralose (E955), simethicone emulsion (simethicone, polysorbate 65, methylcellulose, polyethelene, glycolmonostearate, glycerol monostrearate, xanthan gum, benzoic acid [E210], sorbic acid and purified water), purified water (see also section 2 ‘ZTALMY contains sodium’; ‘ZTALMY contains sodium benzoate’, ‘ZTALMY contains benzoic acid’, ‘ZTALMY contains benzyl alcohol’, and ‘ZTALMY contains methyl parahydroxybenzoate and propyl parahydroxybenzoate’).

What ZTALMY looks like and contents of the pack

ZTALMY is a white to off-white oral suspension. It comes in a plastic bottle which has a plastic child-resistant cap. Each bottle contains 110 mL of oral suspension.

ZTALMY is supplied in packs of either:

- one bottle of oral suspension, two 12 mL and two 3 mL oral dosing syringes, and one bottle adaptor; or
- five bottles of oral suspension, five 12 mL oral dosing syringes, and five bottle adaptors.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Manufacturer

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Finnabair Industrial Estate
Dunkalk, A91 P9KD
Ireland

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