

Package leaflet: Information for the patient

Althea Cosmic T-25 Dried Floral Bud

250mg of delta-9-tetrahydrocannabinol (as THC and THC-acid), less than 10mg of cannabidiol (as CBD and CBD-acid) per gram (g)

Read all of this leaflet carefully before you or the patient start taking this medicine because it contains important information for you.

- 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.
- 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 is Althea Cosmic T-25 is and what it is used for.
2. What you need to know before taking Althea Cosmic T-25.
3. How you should take Althea Cosmic T-25.
4. Possible side effects.
5. How to store Althea Cosmic T-25.
6. Contents of the pack and other information.

1. What is Althea Cosmic T-25 & what is it used for

Althea Cosmic T-25 dried herb for vaporisation consisting of whole dried floral buds, is green in colour with trichomes and has a characteristic aroma. Besides cannabidiol and delta-9-tetrahydrocannabinol, Althea Cosmic T-25 contains lesser amounts of minor cannabinoids, terpenes and other phytochemicals.

2. What you need to know before you take Althea Cosmic T-25

Do not take Althea Cosmic T-25

- if you are allergic to cannabis or any of the other ingredients in this medicine (listed in section 6). Symptoms of an allergic reaction may include shortness of breath, gasping for breath, or difficulty breathing; swelling of the face, lips, tongue, or other parts of the body; rash, itching, or hives on the skin.
- if you or anyone directly related to you has or had a serious mental health disorder such as psychosis. This does not include depression that has resulted from your condition.
- if you are pregnant or planning on becoming pregnant or breastfeeding.
- if you have an unstable cardiovascular disease.

Warnings and precautions:

Talk to your doctor before taking Althea Cosmic T-25 if:

- You have kidney or liver problems.
- You are experiencing psychiatric symptoms. Psychiatric symptoms can include sleep or appetite changes, mood changes, problems with concentration or logical thought.
- Althea Cosmic T-25 may impair your ability to drive as it can make you feel sleepy and sedated.

Children and adolescents

There is no information on the use of this product in patients under the age of 18. Althea Cosmic T-25 is therefore not recommended for patients under the age of 18.

Other medicines and Althea Cosmic T-25:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Taking Althea Cosmic T-25 with certain other medicines may cause side effects, affect how the other medicines work, or affect how Althea Cosmic T-25 works. Do not start or stop other medicines without talking to your doctor or pharmacist. Tell your doctor if you are taking any of the following medicines:

- Medicines that are used to treat seizures such as clobazam, valproate, stiripentol, phenytoin, lamotrigine, carbamazepine and phenobarbital.
- Medicines used to treat infections such as ketoconazole, itraconazole, ritonavir, clarithromycin, rifampicin and propofol.
- St. John's wort (*Hypericum perforatum*) (a herbal medicine used to treat mild anxiety)
- Coumarins, statins, beta-blockers or corticosteroids.
- Calcineurin inhibitors such as ciclosporin or tacrolimus or mTOR inhibitors such as everolimus, sirolimus and temsirolimus.
- Hypnotics, anti-spasticity agents, sedatives or medicines with the potential to cause sedation. Althea Cosmic T-25 can cause tiredness, sleepiness and sedation and so has the potential to increase the sedative or muscle relaxing effects of other drugs.

It is unknown whether Althea Cosmic T-25 reduces the effectiveness of hormonal contraceptives. If taking a hormonal contraceptive, use an additional barrier contraceptive while taking this medicine.

Althea Cosmic T-25 with alcohol

Althea Cosmic T-25 can cause tiredness, sleepiness, and sedation. It may interact with alcohol, affecting co-ordination, concentration, and the ability to react quickly.

Pregnancy, breastfeeding and fertility

If you are pregnant, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. You should not take Althea Cosmic T-25 while you are pregnant unless the doctor decides the benefits outweigh the potential risks, as Althea Cosmic T-25 is likely to cross the placenta. You should not breast-feed whilst taking Althea Cosmic T-25, as Althea Cosmic T-25 may be present in breast milk.

Driving and using machines

Althea Cosmic T-25 may impair your ability to drive as it can make you feel sleepy and sedated. If this happens do not drive or use tools or machinery. Do not drink alcohol.

Do not drive while taking this medicine until you know how it affects you.

Do not drive if you feel sleepy, dizzy, unable to concentrate or make decisions, or if you have blurred or double vision.

3. How to take Althea Cosmic T-25

Althea Cosmic T-25 is cannabis dried flower to be inhaled through a TGA-approved vaporiser. Smoking Althea Cosmic T-25 is not recommended.

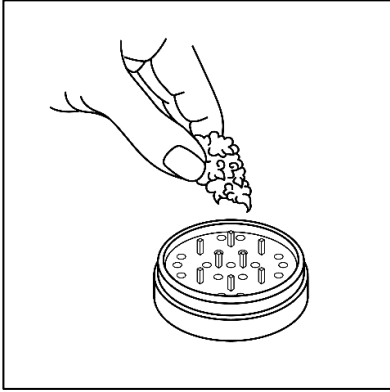
Your doctor will tell you how many doses to take each day, and how much (number in grams) you should take at each dose. The amount of the medicine you need depends on your individual needs. Each person may need a different dose to achieve the best relief from their condition, while minimizing any side effects.

It is always advisable to start at the lowest possible dose and increase the dose very slowly, separating each dose by at least 6 hours. When you find the amount of the medicine that works best for your condition, keep taking this dose unless your doctor advises otherwise. Finding your best dose may take from a few days to several weeks.

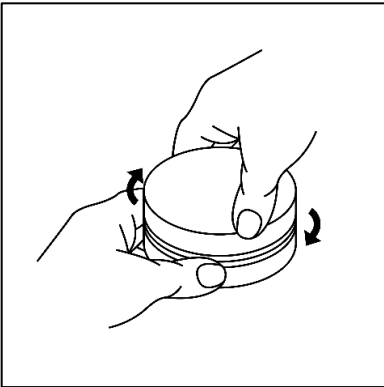
If you have unwanted side effects, speak to your doctor or pharmacist.

Althea Cosmic T-25 is for vaporisation, using a vaporisation device. You may also need a conventional grinder and scales. The manufacturer's instructions for the vaporisation device, the conventional grinder and the scales should be closely followed.

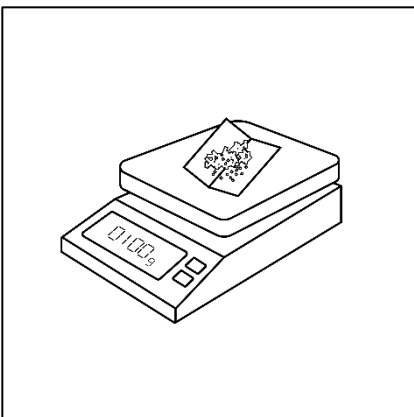
Step 1: Remove the desired amount of flower from its container. If the seal is broken, contact your pharmacy immediately.



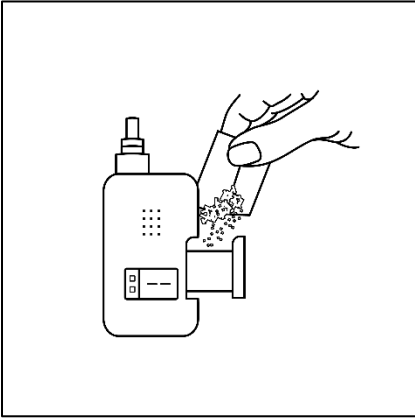
Step 2: Grind the desired amount of flower using a conventional grinder.



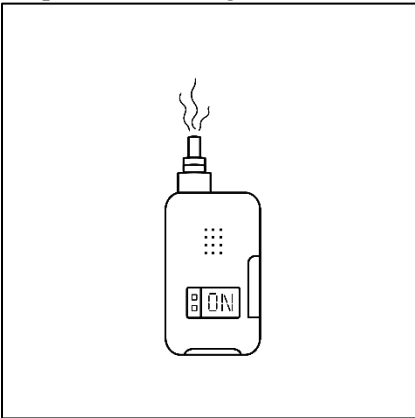
Step 3: Using scales, weigh the correct amount of ground flower for the prescribed dose.



Step 4: Insert the ground flower into the vaporisation device as per the device instructions.



Step 5: Heat the ground flower at the temperature recommended in the device instructions (an example of an appropriate temperature is 180-190°C), until it begins to form vapour. Reduce the temperature if it begins to burn.



If you take more Althea Cosmic T-25 than you should

If you accidentally take more Althea Cosmic T-25 than you should, tell a doctor or pharmacist immediately, or contact your nearest hospital emergency department and take the medicine with you.

If you forget to take Althea Cosmic T-25

If you forget to take a dose, take the next dose at your regular time. Do not double dose to make up for the forgotten dose. If you miss multiple doses, discuss your dosing schedule with your doctor.

If you stop taking Althea Cosmic T-25

Do not stop taking Althea Cosmic T-25 without first talking to your doctor. 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 are most likely to get side effects when you start your treatment. Most side effects are usually mild and wear off quickly. The extent of side effects may vary between individuals.

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

- Palpitations
- Increased heart rate
- Blurred vision
- Diarrhoea
- Dry mouth
- Gastrointestinal disturbance
- Nausea
- Vomiting
- Feeling tired
- Decreased appetite
- Increased appetite
- Feeling disorientated
- Dizziness
- Euphoria
- Feeling sleepy or drowsy
- Difficulty thinking or performing basic tasks
- Feeling agitated
- Feeling anxious
- Confusion
- Difficulty sleeping
- Feeling irritable
- Feeling paranoid
- Cough
- Rash

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 Yellow Card Scheme at 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 Althea Cosmic T-25

Keep out of reach and sight of children.

Do not use after the expiry date printed on the product label.

Store Althea Cosmic T-25 upright below 25°C. Do not refrigerate. Keep away from heat and direct sunlight.

Do not throw away any medicine in the wastewater or household waste. Any unused or left-over medicine, or medicine past its expiry date, should be returned to a pharmacy. Ask your pharmacist if you have questions.

6. Contents of the pack and other information

What Althea Cosmic T-25 contains:

Each gram of Althea Cosmic T-25 250mg of delta-9-tetrahydrocannabinol (as THC and THC-acid) and less than 10mg of cannabidiol (as CBD and CBD-acid).

The product may also contain lesser amounts of minor cannabinoids, terpenes and other phytocannabinoids.

What Althea Cosmic T-25 looks like and contents of the pack:

Althea Cosmic T-25 consists of whole dried floral buds, is green in colour with trichomes and has a characteristic aroma. It comes in an opaque PET jar with a child-resistant screw cap and tamper-evident seal.

Sponsor:

Althea Cosmic T-25 does not currently hold Marketing Authorisation.

Althea Cosmic T-25 is sponsored by:

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