

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

Trinicet 10 mg soft gelatine capsule

Cetirizine dihydrochloride

Contains sugar: Sorbitol 44 mg

Trinicet is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use Trinicet carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Trinicet with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 3 days.

What is in this leaflet

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

1. What Trinicet is and what it is used for

Trinicet contains the active substance cetirizine dihydrochloride.

Trinicet is an anti-allergic medicine.

In adults and children aged 6 years and above, Trinicet is indicated for:

- Allergic rhinitis, hay fever.

- Allergic skin condition associated with pruritus e.g., urticaria.

2. What you need to know before you take Trinicet

Do not take Trinicet:

- if you are hypersensitive (allergic) cetirizine dihydrochloride, hydroxyzine, piperazine or to any of the other ingredients of Trinicet (listed in section 6);
- if you have a severe kidney disease (severe renal failure with creatinine clearance below 30 ml/min);
- if you are pregnant or breastfeeding your baby.

The use of Trinicet is not recommended in children less than 6 years since this formulation does not allow for appropriate dose adaptation.

Warnings and precautions

Take special care with Trinicet:

- If you are drinking alcohol. It is not advised to drink alcohol while taking Trinicet.
- If you are an epileptic patient or a patient at risk of convulsions, you should ask your doctor for advice.
- If you have factors that may cause urinary retention e.g., spinal cord lesion, enlarged prostate (prostatic hyperplasia), you must be careful using Trinicet since it can increase the symptoms.
- Severe skin reactions such as acute generalised exanthematous pustulosis (AGEP) have been reported very rarely with cetirizine-containing products, such as Trinicet. This acute skin reaction may start to show early or delayed signs with numerous small liquid filled blisters arising on a widespread red, inflamed part of the skin, localised on the skin folds, upper body, and upper limbs, which may be accompanied by fever. You will be closely monitored.

If your symptoms persist or worsen, or if new symptoms occur, you should stop taking

Trinicet and consult your doctor.

- If you have a pre-existing liver disease.

Other medicines and Trinicet

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

There are currently no interactions recorded between Trinicet and other medicines.

Trinicet can reduce the accuracy of allergy skin tests. A wash-out period of 3 days is recommended before performing them.

Pregnancy and, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before taking Trinicet.

Driving and using machines

Trinicet can cause drowsiness and/or sleepiness. This effect can be made worse by taking Trinicet with alcohol or other sleep-inducing substances since it can further reduce alertness. Do not drive or use machines until you are aware how Trinicet affects you.

3. How to take Trinicet

Do not share medicines prescribed for you with any other person.

Always take Trinicet exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is:

Adults or children 12 years of age or older: One 10 mg soft gelatine capsule daily

Children 6 to 12 years old: One 10 mg soft capsule daily

Your doctor will tell you how long your treatment with Trinicet will last. Do not stop treatment with Trinicet unless your doctor tells you too.

If you have the impression that the effect of Trinicet is too strong or too weak, tell your doctor or pharmacist.

If you take more Trinicet than you should

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take use Trinicet

If you forget to take your medicine, take it as soon as you remember. Then take the next dose at the usual time. Do not take a double dose or extra capsule to make up for your forgotten dose.

If you stop taking Trinicet

Rarely, pruritus (intense itching) and/or urticaria may return if you stop taking Trinicet.

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

4. Possible side effects

Trinicet can have side effects.

Not all side effects reported for Trinicet are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Trinicet, please consult your health care provider for advice.

If any of the following happens, stop taking Trinicet and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause

difficulty in swallowing or breathing,

- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious reaction to Trinicet. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Less urine than is normal for you, or difficulty urinating, swelling of hands, lower legs or feet, a fever with pain in your lower back. It may mean that you have serious kidney problems.
- You notice your heart beating faster than normal.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent

- Sleepiness
- Headache, dizziness
- Sore throat, difficulty swallowing
- Dry mouth, feeling sick
- Feeling tired

Less frequent

- Increased appetite
- Stomach pain
- Feeling frustrated, aggressiveness, feeling confused or feeling very down, seeing or hearing things that are not real, not being able to fall asleep
- An abnormal sensation, typically tingling or pricking ('pins and needles'), involuntary spasms of muscles (convulsions), weak muscles, shaking, memory loss or difficulty

remembering

- Blurred eyesight, struggling to focus with your eyes, uncontrolled eye-rolling
- Spinning sensation in your head
- Rash, hives, itching
- Joint pain
- Abnormal physical weakness or lack of energy, a general feeling of discomfort or illness, swelling of hands or feet
- Increased weight

In children 6 months to 12 years the following side effects have been noticed:

Frequent

- Sleepiness
- Runny nose
- Loose/runny stomach
- Feeling tired.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of Trinicet.

The applicant can be reached at the following contact number: 010 045 2500.

5. How to store Trinicet

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Store in the original package.
- There are no special storage instructions for Trinicet
- Do not store in a bathroom
- Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

What Trinicet contains

- The active substance is cetirizine dihydrochloride.
- The other ingredients are: Gelatine, macrogol, partially dehydrated liquid sorbitol, sodium hydroxide.

What Trinicet looks like and contents of the pack

White, opaque HDPE container with white opaque HDPE screw cap with induction sealing.

Pack sizes of 25's, 40's and 84's.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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