

SINZAC CAPSULES “S.T.”

Fluoxetine (20mg)

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What Sinzac Capsules is used for

Sinzac Capsules is used for the treatment of:

- Symptoms of depressive illness, with or without associated anxiety symptoms
- Obsessive-compulsive disorder (OCD): persistent, obsessive thoughts that make you carry out repetitive behaviour
- Pre-menstrual Dysphoric Disorder (PMDD): a severe form of premenstrual syndrome that affect the woman's daily activities and relationship with others before menstruation

How Sinzac Capsules Works

Sinzac Capsules contains the active ingredient fluoxetine. Fluoxetine belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs) antidepressants. The antidepressant and antiobsessive-compulsive actions of fluoxetine are presumed to be linked to its inhibition to reuptake of serotonin by the nerve cells in the brain.

Before you use Sinzac Capsules

- When you must not use it

Do not take Sinzac Capsules:

- If you are allergic or hypersensitivity to Sinzac Capsules, any other fluoxetine medicine or any other ingredients in this product (see section **Product description**)

- Before you start to use it

You should check with your doctor:-

- If you are or think you may be pregnant
- If you are planning to become pregnant
- If you are breastfeeding
- If you have diabetes
- If you have kidney disease
- If you have liver disease
- If you have history of heart failure and other cardiovascular diseases
- If you plan or are undergoing surgery

- If you have a history of bleeding disorder
- If you have a history of seizures (fits)
- If you have a history of mania (feeling elated or over-excited, which causes unusual behaviour)
- If you have thoughts or actions relating to self-harm or suicide
- If you have electroconvulsive therapy (ECT) (usually used for severe depression)

- Taking Other Medicines

Some medicines may be affected by Sinzac Capsules, or may affect how well it works. It is important to tell your doctor or pharmacist about all the medicines that you are taking, including those obtained without doctor's prescription. You should talk to your doctor or pharmacist if you are on following :-

- Monoamine oxidase inhibitors (MAOIs)
- Other medicines for depression, such as tricyclic antidepressants (TCAs)
- Medicines used to treat mental illness, such as lithium
- Medicines used to control pain, such as tramadol
- Medicines used to relieve migraine, such as triptans
- Medicines used to treat seizures (fits), such as phenytoin and carbamazepine
- Medicines used to treat heart conditions such as digoxin, propafenone, flecainide
- Blood-thinning medicines or medicines with bleeding risks, such as warfarin and aspirin, and nonsteroidal anti-inflammatory drugs (NSAID)
- St John's Wort (*Hypericum perforatum*)

Other medicines not listed above may also interact with Sinzacs Capsules.

How to use Sinzac Capsules

- How much to use

You should take Sinzac Capsules exactly as advised by your doctor or pharmacist. The amount you take each day will depend on your condition. Do not take more or less than what your doctor prescribes. The usual initial dose for adults is 20 mg. Normal daily dose ranges from 20 mg to 60 mg per day in divided doses.

Use in children and adolescents under 18 years of age:

This product is not indicated for pediatric use. If you have liver problems or concurrent diseases or if you are taking multiple medicines, your doctor may prescribe you a lower dose.

- When to use it

Sinzac Capsules is to be taken twice or three times daily with or without meal. The frequency of dosing depends on your condition. Swallow the capsules with water.

- How long to use it

It is important to take Sinzac Capsules as long as your doctor prescribes

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

If you are not sure what to do, consult your doctor or pharmacist for advice.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Symptoms of an overdose may include nausea, vomiting, restlessness, excitement, and fits.

While you are using it

- Things you must do

Take Sinzacs Capsules exactly the way as prescribed. Tell your doctor or pharmacists immediately if you:

- become pregnant while taking this medication.
- have significant weight loss.
- have new episodes of fits.
- feel restless and feel like you can't sit or stand still.
- have thoughts of harming or killing yourself at any time.

- Things you must not do

Do not share your medicine with others even if they have the same diagnosis as you. Do not stop taking Sinzac Capsules, or lower the dose, without first checking with your doctor.

Your doctor may want you to gradually reduce the amount of Sinzac Capsules you are taking before stopping completely. This should help reduce the chance of withdrawal symptoms (such as nausea,

dizziness, difficulty in getting asleep, anxiety and headache).

**- Things to be careful of
Driving and using machines**

Sinzac Capsules may affect your ability to drive or use machines. Do not drive or use machine until you know how it affects you. Avoid drinking alcohol during your treatment with Sinzac Capsules.

Suicidality in Children and Adolescent:

Sinzac Capsules should normally not be used for children and adolescents under 18 years. Sinzac Capsules increases the risk of suicidal ideation and behaviour in children. Despite this, your doctor may prescribe Sinzac Capsules for patients under 18 when he/she decides that this is in their best interests.

If your doctor has prescribed Sinzac Capsules for a patient under 18 and you want to discuss this, please go back to your doctor. Families or caregivers should pay close attention to your child whenever Sinzac Capsules is started or its dose is changed. Contact your doctor if you notice any sudden or unusual changes in your child's behaviour.

Side Effects

Like all medicines, Sinzac Capsules can cause side effects, although not everybody gets them.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- Itching, skin rash, skin peeling or blistering
- Swelling of the face, lips, tongue or other parts of the body
- Symptoms of serotonin syndrome, such as extremely high fever, muscle rigidity, rapid heartbeat, confusion, extreme restlessness and coma.
- Hallucination (hearing voices or seeing things which are not there) or sudden mood swings to overactivity.
- Fits
- Photosensitivity (abnormally high sensitivity to sunlight)

If you encounter any other side effects not in this list, please inform your doctor or Pharmacist as well.

You may report any side effect or adverse drug reaction directly to the National Centre for Adverse Drug Reaction Monitoring by calling 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers→Reporting).

Storage and Disposal of Sinzac Capsules

- Storage

Store at below 30°C. Protect from light.

- Disposal

If you have any unwanted capsules, do not put them in waste water or household rubbish. Ask your pharmacist how to dispose of the capsules. These measures will help to protect the environment.

Product Description

- What it looks like

It is a white, or almost white powder, filled in the No.4 capsule; the colour of the capsular cap is pale-green, the colour of the capsular body is cream-white. With a ST017 one side, and a SINZAC 20MG on the other side.

- Ingredients

- Active Ingredient
 - Fluoxetine
- Inactive Ingredients
 - Avicel
 - Corn Starch
 - Glycolate
 - Aerosil
 - DL- Malic acid

- MAL number

MAL07061435A

Manufacturer

Taiwan Boitech CO., LTD
22, Chieh Shou Road Taoyuan Taiwan.

Product Registration Holder

Sunward Pharmaceutical Sdn. Bhd.
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