APPROVED PATIENT INFORMATION LEAFLET

Please read this leaflet carefully before taking Zydus-Fluoxetine 20mg capsules.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

Scheduling Status: Schedule 5

Proprietary name, Strength and Pharmaceutical Form:

ZYDUS-FLUOXETINE 20MG capsules (each capsule contains Fluoxetine hydrochloride equivalent to 20 mg Fluoxetine).

1. WHAT ZYDUS-FLUOXETINE 20MG CONTAINS

Active ingredient: Fluoxetine hydrochloride.

Inactive ingredients: Pregelatinized starch and hard gelatine capsule size 2.

2. WHAT ZYDUS-FLUOXETINE 20MG IS USED FOR

Fluoxetine is indicated for the treatment of:

- Major depressive disorders
- Obsessive-compulsive disorder
- An eating disorder called Bulimia nervosa

3. BEFORE YOU TAKE ZYDUS-FLUOXETINE 20MG

Do not take Zydus-Fluoxetine 20mg:

- If you are hypersensitive (allergic) to Fluoxetine or any of the other ingredients (see “WHAT ZYDUS-FLUOXETINE CONTAINS”).
- If you suffer from severe renal function impairment.

- If you are on anti-depressant medication (monoamine oxidase inhibitors, e.g. phenelzine, tranylcypromine and selegiline).

Take special care with Zydus-Fluoxetine 20mg:

- Stop taking Zydus-Fluoxetine 20mg if you experience a combination of the below mentioned symptoms:

  Muscle spasms, agitation, sweating and diarrhoea, confusion, disorientation, hyper-reflexia, tremor, rigidity, incoordination and fever.
- Treatment with Zydus-Fluoxetine should be discontinued if you develop a rash or allergic reaction.
- If you experience worsening of your depression and/or the emergence of suicidal ideation and behaviour, immediately inform your doctor.
- Do not stop taking your capsules without consulting your doctor. The frequency of taking Fluoxetine should be decreased slowly.

Inform your doctor if you suffer from any of the following:

- Fits
- Any heart dysfunction
- Bleeding disorders
- High blood sugar or if you are underweight.
- Any liver or kidney disease
- A disease called Parkinson's

Taking Zydus-Fluoxetine 20mg with food or drink:

ZYDUS- FLUOXETINE 20MG can be administered with or without food. Avoid the use of alcohol.

Pregnancy and breast-feeding:

If you are pregnant or breast feeding your baby while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice. The use of Zydus-Fluoxetine 20mg during pregnancy and breast-feeding has not been proven.

Using other medicines with Zydus-Fluoxetine 20mg:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of Zydus-Fluoxetine 20mg with these medicines may cause undesirable interactions. Tell your doctor or pharmacist if you are taking any other medicines, including any you have bought at your pharmacy, supermarket or health food shop. Please consult your doctor, pharmacist or other healthcare professional for advice.

Concurrent use of Zydus-Fluoxetine 20mg with the following agents can have unwanted interactions:

- Monoamine oxidase inhibitors are a specific anti-depressant medication group. The use of Fluoxetine with any of the following should be avoided: phenelzine, tranylcypromine and selegiline.
- Lithium (psychotic mediation).
- Anti-epiliptic medication (phenytoin and carbamazepine), diazepam, alprazolam, haloperidol (psychiatric drug), clozapine, imipramine and desipramine (anti-depressants).
- Tryptophan.
- Blood thinning agents e.g. warfarin.

4. HOW TO USE ZYDUS-FLUOXETINE 20MG

Always take Zydus-Fluoxetine 20mg exactly as your doctor has instructed you. You should check with your doctor if you are unsure. If you have the impression that the effect of Zydus-Fluoxetine 20mg is too strong or too weak, talk to your doctor or pharmacist.

Depressive disorders:

Adults: 20 mg daily, preferably in the morning.

Obsessive compulsive disorder:

Adults: 20 mg – 60 mg daily

Bulimia nervosa:

Adults: 60 mg daily

Caution is advised in the elderly: dosages above 20 mg daily are not recommended.

If you take more Zydus-Fluoxetine 20mg than you should:

In the event of overdosage, consult your doctor or seek help at the nearest hospital or poison control centre.

If you forget to take Zydus-Fluoxetine 20mg:

Do not take a double dose to make up for the forgotten individual doses. Continue to take the next capsule at the usual time. If you have trouble remembering when to use your medicine, ask your pharmacist for some hints.

DO NOT STOP TAKING YOUR TABLETS WITHOUT CONSULTING YOUR DOCTOR.

5. POSSIBLE SIDE EFFECTS

ZYDUS-FLUOXETINE 20MG can have side effects. Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happen, tell your doctor immediately or go to the casualty department at your nearest hospital:

- Accelerated heart beat.

- Trouble breathing accompanied by a severe skin rash and swelling of the hands, feet lips and mouth.
- Suicidal behaviour.

These are all very serious side effects. You may need urgent medical attention. Except for skin rash which occurs frequently, the rest occurs less frequently.

Tell your doctor if you notice any of the following:

- Headache, nervousness, anxiety and drowsiness.
- Weight loss.
- Diarrhoea, nausea, dyspepsia, anorexia and vomiting.
- Decreased libido, sexual dysfunction.

The above mentioned side-effects occur frequently.

Less frequently reported side-effects are:

- Fatigue, insomnia, tremor, overall weakness, dizziness, abnormal dreams, agitation, seizures, elated feeling and loss of voluntary muscle movement.
- Visual disturbances and muscle pain.
- Troubled breathing, lung inflammation and/or fibrosis.

6. STORING AND DISPOSING OF ZYDUS-FLUOXETINE 20MG

- Store below 25 ºC. Protect from light. Do not remove the blister from the outer carton until required for use.
- KEEP ALL MEDICINES OUT OF REACH OF CHILDREN
- Do not use the capsules after the expiry date printed on the container.
- Return all unused medicine to your pharmacist
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets)

7. PRESENTATION OF ZYDUS-FLUOXETINE 20MG

Aluminium/PVdC blister strips containing 10 capsules. 3 x 10 capsules per outer carton.

8. IDENTIFICATION OF ZYDUS-FLUOXETINE 20MG

A hard gelatine capsule with an opaque light-green coloured cap and an opaque ivory coloured body containing a white to off-white powder.

9. REGISTRATION NUMBER

37/1.2/0265

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Zydus Healthcare SA (Pty) Ltd.

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11. DATE OF PUBLICATION:

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