OXETINE®20 mg Film-Coated Tablets

Read all of this leaflet carefully before you start taking this medicine.

- □ Keep this leaflet. You may need to read it again. $\hfill \square$ If you have any further questions, ask your doctor or your pharmacist.
- ☐ This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their
- symptoms are the same as yours. $\ \square$ If any of the side effects gets serious or if you notice any side effects not listed in the leaflet, please tell your doctor or pharmacist.

In this leaflet:

- 1. What OXETINE is and what it is used for
- 2. Before you take **OXETINE**
- 3. How to take **OXETINE**
- 4. Possible side effects5. How to store **OXETINE**
- 6. Further information
- 1. WHAT OXETINE IS AND WHAT IT IS USED FOR **OXETINE** Film-Coated Tablets contain the active

substance Fluoxetine which is one of a group of medicines called selective serotonin re-uptake inhibitors (SSRI) antidepressants. This medicine is used to treat the following conditions:

Adults:

- □ Major depressive episodes.
- $\hfill\Box$ Obsessive-compulsive disorder. □ Bulimia nervosa: **OXETINE** is used alongside psychotherapy for the reduction of binge-eating and
- Children and adolescents aged 8 years and above: Moderate to severe major depressive disorder, if the depression does not respond to psychological therapy

after 4-6 sessions. **OXETINE** should be offered to a child or young person with moderate to severe major depressive disorder only in combination with psychological therapy 2. BEFORE YOU TAKE OXETINE Do not take OXETINE if you are:

$\hfill \square$ Allergic to Fluoxetine or any of the other ingredients of this medicine (listed in section 6). If you develop a

iproniazid used to treat depression).

Take special care with OXETINE:

- rash or other allergic reactions (like itching, swollen lips or face or shortness of breath), stop taking the tablets straight away and contact your doctor immediately. □ Taking other medicines known as irreversible non-selective monoamine oxidase inhibitors (MAOIs), since serious or even fatal reactions can occur (e.g.
- Treatment with **OXETINE** should only be started at least 2 weeks after discontinuation of an irreversible, non-selective MAOI. Do not take any irreversible, non-selective MAOIs for at
- least 5 weeks after you stop taking **OXETINE**. If OXETINE has been prescribed for a long period and/or at a high dose, a longer interval needs to be considered by your doctor.
- Talk to your doctor or pharmacist before taking **OXETINE** if any of the following applies to you: □ Heart problems;

- Taking metoprolol (to treat heart failure) since there is an increased risk of your heart beat becoming too slow.

- □ Appearance of fever, muscle stiffness or tremor, changes in your mental state like confusion, irritability and extreme agitation; you may suffer from the so-called "serotonin syndrome" or "neuroleptic
- malignant syndrome". Although this syndrome occurs rarely it may result in potentially life threatening conditions; contact your doctor immediately, since OXETINE might need to be discontinued. □ Mania now or in the past; if you have a manic episode, contact your doctor immediately because **OXETINE** might need to be discontinued. □ History of bleeding disorders or appearance of
- pregnancy). $\hfill \square$ Ongoing treatment with medicines that thin the blood (see 'Other medicines and **OXETINE**').

 □ Epilepsy or fits. If you have a fit (seizures) or experience an increase in seizure frequency, contact

bruises or unusual bleeding or if you are pregant (see

- your doctor immediately; OXETINE might need to be discontinued □ Ongoing ECT (electro-convulsive therapy) □ Ongoing treatment with tamoxifen (used to treat breast cancer) (see 'Other medicines and OXETINE'). □ Starting to feel restless and cannot sit or stand still
- (akathisia). Increasing your dose of **OXETINE** may make this worse.
- $\hfill\Box$ Diabetes (your doctor may need to adjust your dose of insulin or other antidiabetic treatment). □ Liver problems (your doctor may need to adjust your dosage).
- □ Low resting heart-rate and/or if you know that you may have salt depletion as a result of prolonged severe diarrhoea and vomiting (being sick) or usage of diuretics (water tablets)
- $\hfill\Box$ Ongoing treatment with diuretics (water tablets), especially if you are elderly Glaucoma (increased pressure in the eye)
- If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to

depression or anxiety disorder:

Thoughts of suicide and worsening of your

- work, usually about two weeks but sometimes longer. You may be more likely to think like this:

 □ If you have previously had thoughts about killing or harming yourself. $\hfill\Box$ If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behavior in adults aged less than 25 years with psychiatric
- straight away. You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder and ask them to read this leaflet. You might ask them to

tell you if they think your depression or anxiety is

vour behaviour.

conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at

any time, contact your doctor or go to a hospital

Children and adolescents aged 8 to 18 years: Patients under 18 have an increased risk of side-effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when they take this class of medicines **OXETINE** should only be used in children and adolescents aged 8 to 18 years for the treatment of

moderate to severe major depressive episodes (in

not be used to treat other conditions.

Additionally, only limited information concerning the

combination with psychological therapy) and it should

getting worse, or if they are worried about changes in

long-term safety of OXETINE on growth, puberty mental, emotional and behavioural development in this age group is available. Despite this, and if you are a patient under 18, your doctor may prescribe OXETINE for moderate to severe major depressive episodes, in combination with psychological therapy, because he/she decides that this is in your best interests. If your doctor has prescribed **OXETINE** for a patient under 18 and you want to discuss this, please go back to your doctor. You should inform your doctor if any of the

Sexual dysfunction Medicines like OXETINE (so called SSRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after

symptoms listed above develop or worsen when

OXETINE should not be used in the treatment of

patients under 18 are taking OXETINE.

children under the age of 8 years

Taking other medicines with OXETINE: Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

stopping treatment.

Do not take **OXETINE** with: Certain irreversible, non-selective monoamine oxidase inhibitors (MAOIs) some used to treat depression. Irreversible, non-selective MAOIs must not be used with $\ensuremath{\textbf{OXETINE}}$ as serious or even fatal

reactions (serotonin syndrome) can occur (see section

"Do not take **OXETINÉ**"). Treatment with **OXETINE**

should only be started at least 2 weeks after discontinuation of an irreversible, non-selective MAOI (for instance tranylcypromine). Do not take any irreversible, non-selective MAOIs for at least 5 weeks after you stop taking OXETINE. If OXETINE has been prescribed for a long period and/or at a high dose, a longer interval than 5 weeks may need to be

considered by your doctor. $\hfill \square$ metoprolol when used for heart failure; there is an increased risk of your heart beat becoming too slow. OXETINE may affect the way the following medicines work (interaction):

□ Tamoxifen (used to treat breast cancer), because **OXETINE** may change the blood levels of this drug resulting in the possibility of a reduction in the effect of tamoxifen, your doctor may need to consider prescribing a different antidepressant treatment. □ Monoamine oxidase inhibitors A (MAOI-A) including moclobemide, linezolid (an antibiotic) and methylthioninium chloride (also called methylene blue, used for the

- treatment of medicinal or chemical product induced methemoglobinemia): due to the risk of serious or even fatal reactions (called serotonin syndrome). Treatment with fluoxetine can be started the day after stopping treatment with reversible MAOIs but the doctor may wish to monitor you carefully and use a lower dose of the MAOI-A drug. □ Mequitazine (for allergies), because taking this drug
- with **OXETINE** may increase the risk of changes in the electrical activity of the heart.
- $\hfill\Box$ Phenytoin (for epilepsy), because OXETINE may influence the blood levels of this drug, your doctor may need to introduce phenytoin more carefully and carry

out check-ups when given with **OXETINE**.

□ Lithium, selegiline, St. John's Wort, tramadol (a

painkiller), triptans (for migraine) and tryptophan, there

is an increased risk of mild serotonin syndrome when

- Patient Information Leaflet (PIL) Fluoxetine as Fluoxetine Hydrochloride
- these drugs are taken with OXETINE. Your doctor will carry out more frequent check-ups.

 Medicines that may affect the heart's rhythm, e.g. Class IA and III antiarrhythmics, antipsychotics (e.g.
- phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial agents (e.g. sparfloxacin, moxifloxacin, erythromycin IV pentamidine), anti-malaria treatment particularly halofantrine or certain antihistamines (astemizole mizolastine), because taking one or more of these drugs with OXETINE may increase the risk of changes in the electrical activity of the heart.
- □ Anti-coagulants (such as warfarin), NSAID (such as ibruprofen, diclofenac), aspirin and other medicines which can thin the blood (including clozapine, used to treat certain mental disorders). **OXETINE** may alter the effect of these medicines on the blood. If **OXETINE** treatment is started or stopped when you are taking warfarin, your doctor will need to perform certain tests, adjust your dose and check on you more frequently
- □ Cyproheptadine (for allergies), because it may reduce the effect of **OXETINE**. □ Drugs that lower sodium levels in the blood (including, drug that causes increase in urination,
- desmopressin, carbamazepine and oxcarbazepine); because these drugs may increase the risk of sodium levels in the blood becoming too low when taken with □ Anti-depressants such as tricyclic anti-depressants, other selective serotonin reuptake inhibitors (SSRIs) or bupropion, mefloquine or chloroquine (used to treat
- malaria), tramadol (used to treat severe pain) or anti-psychotics such as phenothiazines or butyrophenones, because **OXETINE** may increase the risk of seizures when taken with these medicines. □ Flecainide, propafenone, nebivolol or encainide (for heart problems), carbamazepine (for epilepsy), atomoxetine or tricyclic antidepressants (for example
- imipramine, desipramine and amitriptyline) or risperidone (for schizophrenia); because OXETINE may possibly change the blood levels of these medicines, your doctor may need to lower their dose when administered with OXETINE Taking OXETINE with food, drink and alcohol: $\ \square$ You can take **OXETINE** with or without food,

$\hfill\Box$ You should avoid alcohol while you are taking this medicine.

whatever you prefer.

- **Pregnancy, breastfeeding and fertility:**If you are pregnant or breast-feeding, think you may
- be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice

Pregnancy: □ Talk to your doctor as soon as possible if you're

before taking this medicine.

doctor immediately.

pregnant, if you might be pregnant, or if you're planning to become pregnant. □ In babies whose mothers took fluoxetine during the first few months of pregnancy, there have been some studies describing an increased risk of birth

This increased to about 2 in 100 babies in mothers who took fluoxetine. $\hfill \square$ When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like fluoxetine may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born. If this happens

to your baby you should contact your midwife and/or

□ It is preferable not to use **OXETINE** during

pregnancy unless the potential benefit outweighs

defects affecting the heart. In the general population,

about 1 in 100 babies are born with a heart defect.

- the potential risk. Thus, you and your doctor may decide to gradually stop taking **OXETINE** while you are pregnant or before being pregnant. However, depending on your circumstances, your doctor may suggest that it is better for you to keep taking OXETINE. □ Caution should be exercised when used during pregnancy, especially during late pregnancy or just before giving birth since the following effects have been reported in new born children: irritability, tremor,
- muscle weakness, persistent crying, and difficulty in sucking or in sleeping. □ If you take **OXETINE** near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. your doctor or midwife should be aware that you are taking $\mathbf{OXETINE}$
- so they can advise you. Breastfeeding: Fluoxetine is excreted in breast milk and can cause side effects in babies. You should only breast-feed if it is clearly necessary. If breast-feeding is continued your doctor may prescribe a lower dose of Fluoxetine Fertility:
 Fluoxetine has been shown to reduce the quality of

observed as yet. Driving and using machines: Psychotropic drugs such as OXETINE may affect your judgment or co-ordination. Do not drive or use machinery until you know how OXETINE affects you.

sperm in animal studies. Theoretically, this could affect

fertility, but impact on human fertility has not been

ingredients of OXETINE:

OXETINE tablets contain lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. 3. HOW TO TAKE OXETINE **Adults** Major depressive episodes

Adults and the elderly: The recommended dose is 20

mg daily. Dosage should be reviewed and adjusted if

necessary within 3 to 4 weeks of initiation of therapy and thereafter as judged clinically appropriate Although there may be an increased potential for undesirable effects at higher doses, in some patients,

with insufficient response to 20 mg, the dose may be increased gradually up to a maximum of 60 mg. Dosage adjustments should be made carefully on an individual patient basis, to maintain the patients at the lowest effective dose. Patients with depression should be treated for a sufficient period of at least 6 months to ensure that they are free from symptoms. Obsessive-compulsive disorder Adults and the elderly: The recommended dose is 20 mg daily. Although there may be an increased potential for undesirable effects at higher doses, in some

patients, if after two weeks there is insufficient

response to 20 mg, the dose may be increased

gradually up to a maximum of 60 mg.

If no improvement is observed within 10 weeks, treatment with fluoxetine should be reconsidered. If a good therapeutic response has been obtained, treatment can be continued at a dosage adjusted on an individual basis. While there are no systematic studies to answer the question of how long to continue fluoxetine treatment, OCD is a chronic condition and it is reasonable to consider continuation beyond 10 weeks in responding patients. Dosage adjustments should be made carefully on an individual patient basis, to maintain the patient at the lowest effective dose. The need for treatment should be reassessed periodically. Some clinicians advocate concomitant behavioural psychotherapy for patients who have done well on pharmacotherapy. Long-term efficacy (more than 24 weeks) has not been demonstrated in OCD. Bulimia nervosa Adults and the elderly: A dose of 60 mg/day is recommended. Long-term efficacy (more than $3\,$

The recommended dose may be increased or decreased. Doses above 80 mg/day have not been systematically evaluated.

effective dose.

All indications

nervosa.

aged 8 years and above (Moderate to severe major depressive episode) Treatment should be initiated and monitored under specialist supervision. The starting dose is 10 mg/day.

Dose adjustments should be made carefully, on an

individual basis, to maintain the patient at the lowest

Paediatric population - Children and adolescents

months) has not been demonstrated in bulimia

After one to two weeks, the dose may be increased to 20 mg/day. Clinical trial experience with daily doses greater than 20 mg is minimal. There is only limited data on treatment beyond 9 weeks. Lower weight children:

Due to higher plasma levels in lower weight children, the therapeutic effect may be achieved with lower doses

For paediatric patients who respond to treatment, the need for continued treatment after 6 months should be reviewed. If no clinical benefit is achieved within 9 weeks, treatment should be reconsidered. **Elderly patients**

Caution is recommended when increasing the dose

and the daily dose should generally not exceed 40 mg. Maximum recommended dose is 60 mg/day. Hepatic impairment

A lower or less frequent dose (e.g. 20 mg every second day) should be considered in patients with hepatic impairment, or in patients where concomitant

medication has the potential for interaction with OXETINE. Withdrawal symptoms seen on discontinuation of OXETINE: Abrupt discontinuation should be avoided. When stopping treatment with OXETINE the dose

should be gradually reduced over a period of at least one to two weeks in order to reduce the risk of withdrawal reactions. If intolerable symptoms occur following a decrease in the dose or upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently the physician may continue decreasing the dose, but at a more gradual rate

- - mind when starting or stopping treatment
 - straight away. □ Take the pack of **OXETINE** with you if you can.
 - Symptoms of overdose include: nausea, vomiting, seizures, heart problems (like irregular heart beat and cardiac arrest), lung problems and change in mental
 - condition ranging from agitation to coma.

 If you forget to take OXETINE: If you miss a dose, do not worry. Take your next dose the next day at the usual time. Do not take a double
 - dose to make up for a forgotten dose.

 □ Taking your medicine at the same time each day may help you to remember to take it regularly.
 - If you stop taking OXETINE: □ Do not stop taking **OXETINE** without asking your
 - doctor first, even when you start to feel better. It is important that you keep taking your medicine. □ Make sure you do not run out of tablets. You may notice the following effects (withdrawal effects) when you stop taking OXETINE: dizziness,

tingling feelings like pins and needle, sleep disturbances (vivid dreams, nightmares, inability to

sleep), feeling restless or agitated, unusual tiredness or

weakness, feeling anxious, nausea/vomiting (feeling

sick or being sick), tremor (shakiness), headaches Most people find that any symptoms on stopping OXETINE are mild and disappear within a few weeks. If you experience symptoms when you stop treatment, contact your doctor. When stopping OXETINE, your doctor will help you to

reduce your dose slowly over one or two weeks - this should help reduce the chance of withdrawal effects. 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.

☐ If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital

- straight away. (see section 2) □ If you get a rash or allergic reaction such as itching, swollen lips/tongue or wheezing/shortness of breath, stop taking the tablets straight away and tell your doctor immediately. \square If you feel restless and cannot sit or stand still, you may have akathisia, increasing your
- dose of **OXETINE** may make you feel worse. If you feel like this, contact your doctor.

 ☐ Tell your doctor immediately if your skin starts to turn red or you develop a varied skin reaction or your skin starts to blister or peel. This is very rare. The most frequent sides effects (very common side effects that may affect more than 1 user in 10) are insomnia, headache, diarrhoea, feeling sick (nausea) and fatigue Some patients have had:

 A combination of symptoms (known as "serotonin") syndrome") including unexplained fever with faster breathing or heart rate, sweating, muscle stiffness or
- tremor, confusion, extreme agitation or sleepiness (only rarely).

 Feelings of weakness, drowsiness or confusion mostly in elderly people and in (elderly) people taking diuretics (water tablets). $\ \square$ Prolonged and painful erection

 Irritability and extreme agitation. □ Heart problems, such as fast or irregular heart rate, fainting, collapsing or dizziness upon standing which may indicate abnormal functioning of the heart rate. If you have any of the above side effects, you should
- patients taking OXETINE: Common (may affect up to 1 in 10 people): □ Not feeling hungry, weight loss □ Nervousness, anxiety □ Restlessness, poor concentration

The following side effects have also been reported in

tell your doctor immediately.

- □ Feeling tense □ Decreased sex drive or sexual problems (including difficulty maintaining an erection for sexual activity)

 □ Sleep problems, unusual dreams, tiredness or
- sleepiness

 Dizziness

 Change in taste □ Uncontrollable shaking movements □ Blurred vision □ Rapid and irregular heartbeat sensations
- □ Flushing □ Yawning □ Indigestion, vomiting $\hfill \square$ Dry mouth $\hfill \square$ Rash, urticaria, itching $\hfill \square$ Excessive sweating

 Joint pain

 Passing urine more frequently □ Unexplained vaginal bleeding
- Uncommon (may affect up to 1 in 100 people):

 □ Feeling detached from yourself □ Strange thinking

 □ Abnormally high mood □ sexual problems, including

□ Increased tendency to bruising

(inflammation of

medicines.

Dioxide

Feeling shaky or chills

orgasm problems, occasionally persisting after treatment discontinuation Thoughts of suicide or

- harming yourself

 Teeth grinding Muscle twitching, involuntary movements or problems with balance or co-ordination □ Memory impairment □ Enlarged (dilated) pupils □ Ringing in the ears $\ \square$ Low blood pressure $\ \square$ Shortness of breath
- □ Unexplained bruising or bleeding □ Cold sweat Difficulty passing urine

 Feeling hot or cold □ Abnormal liver test results Rare (may affect up to 1 in 1,000 people):

 □ Low levels of salt in the blood □ Reduction in blood

□ Nose bleeds □ Difficulty swallowing □ Hair loss

- platelets, which increases risk of bleeding or bruising □ Reduction in white blood cell count
 □ Untypical wild behaviour □ Hallucinations
- □ Agitation □ Panic attacks □ Confusion □ Stuttering □ Aggression □ Fits □ Vasculitis
- a blood vessel)

 Rapid swelling of the tissues around the neck, face, mouth and/or throat $\ \square$ Pain in the tube that takes food or water to your stomach □ Hepatitis □ Lung problems □ Sensitivity to sunlight □ Muscle pain □ Problems urinating

 Producing breast milk
- Most of these side effects are likely to disappear with continued treatment. In children and adolescents (8-18 years) - In addition to the possible side effects listed above, OXETINE may slow growth or possibly delay sexual maturity.

Bone fractures - an increased risk of bone fractures

has been observed in patients taking this type of

Suicide-related behaviours (suicide attempt and suicidal thoughts), hostility, mania, and nose bleeds were also commonly reported in children. Frequency not known: □ Heavy vaginal bleeding shortly after birth (postpartum hemorrhage), see pregnancy in section 2 for more information 5. HOW TO STORE OXETINE

□ Do not store above 30°C, protected from light. □ Do not use **OXETINE** after the expiry date which is stated on the carton and on the blister, after (EXP).Date.

□ Keep out of the reach and sight of children.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose

- of medicines no longer required. These measures will help to protect the environment. 6. FURTHER INFORMATION What OXETINE contains:
- Film-Coated Tablet contains Fluoxetine 20mg as Fluoxetine Hydrochloride. □ The other ingredients are: Maize starch, Lactose, Povidone K29-32, Colloidal Anhydrous Silica, Magnesium Stearate, Hydroxypropyl Methylcelluose

Type 2910, Polyethylene Glycol 400, and Titanium

□ The active substance is Fluoxetine. Each **OXETINE**

□ OXETINE 20 Film - Coated Tablet are white to off white, square shallow biconvex shaped film coated tablets with "OX 20" debossed on one side and plain on the other side. □ Boxes of 7 blistered tablets of OXETINE 20.
 □ Boxes of 10 blistered tablets of OXETINE 20.

What OXETINE looks like and contents of the pack:

Health care professionals and patients are encouraged to report adverse events or side effects to JFDA by using: Email: jpc@jfda.jo

□ Boxes of 20 blistered tablets of **OXETINE 20**.

□ Boxes of 30 blistered tablets of OXETINE 20.

Mobile application: (Jordan fda)

Website: www.jfda.jo

Issued in: August 2021

Yellow card form.

THIS IS A MEDICAMENT

- ☐ A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.

 Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who dispensed the medicament.

 The details and the observations are considered in medicine.
- of the pnatriacus wind uspensed one invasion.

 The doctor and the pharmacist are experts in medicine.

 Do not by yourself interrupt the period of treatment prescribed for you.

 Do not repeat the same prescription without consulting your doctor.

 Keep medicaments out of the reach of children. COUNCIL OF ARAB HEALTH MINISTERS UNION OF ARAB PHARMACISTS OX/19/234/01
- Prescribing Information Available Upon Reque
- - JPM The Jordanian Pharmaceutical Manufacturing CO. P.O. BOX 151. Um Al-Amad 16197. JORDAN

- If you take more OXETINE than you should:
- divided dose, during or between meals $\hfill \square$ When dosing is stopped, active drug substances will persist in the body for weeks. This should be borne in
- Method of administration □ For oral administration
 - □ Fluoxetine may be administered as a single or
- - $\hfill \square$ If you take too many Tablets, go to your nearest hospital emergency department or tell your doctor