



this happening

·Change in sex drive or sexual function. For example, lack of orgasm and, in men, abnormal erection and ejaculation.

Common (may affect up to 1 in 10 people)

·Decreased appetite

·Not sleeping well (insomnia) or feeling sleepy

·Abnormal dreams (including nightmares)

·Feeling dizzy or shaky (tremors)

·Headache

·Feeling agitated

·Feeling unusually weak

·Yawning, dry mouth

·Diarrhoea or constipation

·Weight gain

·Sweating

·Increases in cholesterol levels

·Being sick (vomiting)

·Unable to concentrate properly.

Uncommon (may affect up to 1 in 100 people)

·A faster than normal heartbeat

·A brief increase in blood pressure, or a brief decrease in blood pressure that may make you feel dizzy or faint when you stand up suddenly

·Lack of movement, stiffness, shaking or abnormal movements in the mouth and tongue

·Dilated pupils

·Uncontrollable, involuntary passing of urine (urinary incontinence)

If you are a diabetic patient you may notice a loss of control of your blood sugar levels whilst taking PAROXAL. Please speak to your doctor about adjusting the dosage of your insulin or diabetes medications.

Rare (may affect up to 1 in 1,000 people)

·Abnormal production of breast milk in men and women

·A slow heartbeat

·An increase of liver enzymes which can be seen in a blood test

·Panic attacks

·Overactive behaviour or thoughts (mania)

·Feeling detached from yourself (depersonalisation)

·Feeling anxious

·Pain in the joints or muscles

·Irresistible urge to move the legs (Restless legs syndrome)

·Increase in a hormone called prolactin in the blood

·Menstrual period disorders (including heavy or irregular periods, bleeding between periods and absence or delay of periods).

·Very rare (may affect up to 1 in 10,000 people)

·Fluid or water retention which may cause swelling of the arms or legs

·Sensitivity to sunlight

·Painful erection of the penis that won't go away

·Unexplained or unusual bleeding or bruising. These may be signs of having a low blood platelet count.

Not known (frequency cannot be estimated from the available data)

·Aggression

·Buzzing, hissing, whistling, ringing or persistent noise in the ears (Tinnitus).

An increased risk of bone fractures has been observed in patients taking this type of medicines.

In studies of PAROXAL in under 18s, common side effects that affected less than 1 in 10

children/adolescents were: an increase in suicidal thoughts and suicide attempts, deliberately harming themselves, being hostile, aggressive or unfriendly, lack of appetite, shaking, abnormal sweating,

hyperactivity (having too much energy), agitation, changing emotions (including crying and changes in mood). These studies also showed that the same symptoms affected children and adolescents

taking

sugar pills (placebo) instead of PAROXAL, although these were seen less often.

In addition, patients under 18 also commonly (affecting less than 1 in 10) experienced stomach ache, feeling nervous and changing emotions (including crying, changes in mood, trying to hurt themselves,

thoughts of suicide and attempting suicide).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store PAROXAL

Do not store above 25°C. Store in the original package. Keep out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

## 6. Contents of the pack and other information

**What PAROXAL contains**

The active substance is paroxetine.

Each PAROXAL 20 mg film-coated tablet contains 20 mg paroxetine as the hydrochloride anhydrate.

The other ingredients are:

Each PAROXAL 30 mg film-coated tablet contains 30 mg paroxetine as the hydrochloride anhydrate.

The other ingredients: microcrystalline cellulose, calcium hydrogen phosphate dehydrate, copovidone,

crospovidone, colloidal silicon dioxide, opadry II white, talc, magnesium stearate, purified water.

**What PAROXAL look like and contents of the pack**

Box of 30 film-coated of 20 mg paroxetine in blister pack (3 blisters x 10 tablets).

Box of 30 film-coated of 30 mg paroxetine in blister pack (3 blisters x 10 tablets).

**Manufacturer and Marketing Authorisation Holder**

ZADA Pharmaceuticals Ltd.

Donji Bistarac without number

75300 Lukavac

Bosnia and Herzegovina

**Date and number of marketing authorization:**

Δ PAROXAL, 30 film-coated tablets of 20 mg in box:

Number: 04-07.3-2-5041/15

Date: 12.11.2015.

Δ PAROXAL, 30 film-coated tablets of 30 mg in box:

Number: 04-07.3-2-5042/15

Date: 12.11.2015.

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