This document has been electronicaly signed

	Author (OZO)	Approver1 (OZO)	Approver2 (OPTP)
Ime in priimek:	Primc David	Regina Nadja	
Podpis:	primcd	regina	
Datum:	25.11.2019	25.11.2019	

NA./PL.ZALASTA ODT GB/IE prva stran/first page

smer branja kode/direction of reading PhC

70 mm ± 0,5 mm

148 mm ± 0,5 mm

Package leaflet: Information for the user

Zalasta® 5 mg orodispersible tablets
Zalasta® 7.5 mg orodispersible tablets
Zalasta® 10 mg orodispersible tablets
Zalasta® 15 mg orodispersible tablets
Zalasta® 20 mg orodispersible tablets

Olanzapine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Zalasta is and what it is used for

Zalasta contains the active substance olanzapine. Zalasta belongs to a group of medicines called antipsychotics and is used to treat the following conditions:
- Schizophrenia, a disease with symptoms such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn. People with this disease may also feel depressed, anxious or tense.
- Moderate to severe manic episodes, a condition with symptoms of excitement or euphoria.

Zalasta has been shown to prevent recurrence of these symptoms in patients with bipolar disorder whose manic episode has responded to olanzapine treatment.

2. What you need to know before you take Zalasta

Do not take Zalasta
- If you are allergic (hypersensitive) to olanzapine or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may be recognised as a rash, itching, a swollen face, swollen lips or shortness of breath. If this has happened to you, tell your doctor.
- If you have been previously diagnosed with eye problems such as certain kinds of glaucoma (increased pressure in the eye).

Warnings and precautions
Talk to your doctor or pharmacist before you take Zalasta.
- The use of Zalasta in elderly patients with dementia is not recommended as it may have serious side effects
- Medicines of this type may cause unusual movements mainly of the face or tongue. If this happens after you have been given Zalasta tell your doctor.
- Very rarely, medicines of this type cause a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness. If this happens, contact your doctor at once.
- Weight gain has been seen in patients taking Zalasta. You and your doctor should check your weight regularly. Consider referral to a dietician or help with a diet plan if necessary.
- High blood sugar and high levels of fat (triglycerides and cholesterol) have been seen in patients taking Zalasta. Your doctor should do blood tests to check blood sugar and certain fat levels before you start taking Zalasta and regularly during treatment.
- Tell the doctor if you or someone else in your family has a history of blood clots, as medicines like these have been associated with the formation of blood clots.

If you suffer from any of the following illnesses tell your doctor as soon as possible:
- Stroke or "mini" stroke (temporary symptoms of stroke)
- Parkinson's disease
- Prostate problems
- A blocked intestine (Paralytic ileus)
- Liver or kidney disease
- Blood disorders
- Heart disease
- Diabetes
- Seizures
- 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)

If you suffer from dementia, you or your carer/relative should tell your doctor if you have ever had a stroke or "mini" stroke.

As a routine precaution, if you are over 65 years your blood pressure may be monitored by your doctor.

Children and adolescents
Zalasta is not for patients who are under 18 years.

Other medicines and Zalasta
Only take other medicines while you are on Zalasta if your doctor tells you that you can. You might feel drowsy if Zalasta is taken in combination with antidepressants or medicines taken for anxiety or to help you sleep (tranquillisers).

Tell your doctor if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor if you are taking:
- medicines for Parkinson's disease.
- carbamazepine (an anti-epileptic and mood stabiliser), fluvoxamine (an antidepressant), or ciprofloxacin (an antibiotic) - it may be necessary to change your Zalasta dose.

Zalasta with alcohol
Do not drink any alcohol if you have been given Zalasta as together with alcohol it may make you feel drowsy.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. You should not take this medicine when pregnant unless you have discussed this with your doctor.

The following symptoms may occur in newborn babies, of mothers that have used Zalasta in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Driving and using machines
There is a risk of feeling drowsy when you are given Zalasta. If this happens do not drive or operate any tools or machines. Tell your doctor.

Zalasta contains aspartame
This medicine contains 0.50 mg aspartame in each 5 mg orodispersible tablet.
This medicine contains 0.75 mg aspartame in each 7.5 mg orodispersible tablet.
This medicine contains 1.00 mg aspartame in each 10 mg orodispersible tablet.
This medicine contains 1.50 mg aspartame in each 15 mg orodispersible tablet.
This medicine contains 2.00 mg aspartame in each 20 mg orodispersible tablet.

Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

3. How to take Zalasta

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how many Zalasta tablets to take and how long you should continue to take them. The daily dose of Zalasta is between 5 mg and 20 mg. Consult your doctor if your symptoms return but do not stop taking Zalasta unless your doctor tells you to.

You should take your Zalasta tablets once a day following the advice of your doctor. Try to take your tablets at the same time each day. It does not matter whether you take them with or without food.

How to take Zalasta
Zalasta tablets break easily, so you should handle the tablets carefully. Do not handle the tablets with wet hands as the tablets may break up. To take a tablet out of the packaging:
1. Hold the blister at the edges and separate one blister cell from the rest of the blister by gently tearing along the perforations around it.
2. Pull up the edge of the foil and peel foil off completely.
3. Tip the tablet out onto your hand.
4. Put the tablet on the tongue as soon as it is removed from the packaging.

The tablet begins breaking up in the mouth within seconds and can then be swallowed with or without water. Your mouth should be empty before placing the tablet on the tongue.

You can also place the tablet in a full glass or cup of water. Drink it straight away.

If you take more Zalasta than you should
Patients who have taken more Zalasta than they should have experienced the following symptoms: rapid beating of the heart, agitation/aggressiveness, problems with speech, unusual movements (especially of the face or tongue) and reduced level of consciousness. Other symptoms may be: acute confusion, seizures (epilepsy), coma, a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness, slowing of the breathing rate, aspiration, high blood pressure or low blood pressure, abnormal rhythms of the heart. Contact your doctor or hospital straight away if you experience any of the above symptoms. Show the doctor your pack of tablets.

If you forget to take Zalasta
Take your tablets as soon as you remember. Do not take two doses in one day.

If you stop taking Zalasta
Do not stop taking your tablets just because you feel better. It is important that you carry on taking Zalasta for as long as your doctor tells you.

If you suddenly stop taking Zalasta, symptoms such as sweating, unable to sleep, tremor, anxiety or nausea and vomiting might occur. Your doctor may suggest you to reduce the dose gradually before stopping treatment.

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

smer vlaken/direction on fibre

520 mm ± 0,8 mm

70 mm ± 0,5 mm

smer branja kode/direction of reading PhC

Leaflet folded on middle with visibly first side (title); PhC that comes out of the middle of leaflet must be visible!/
Navodila prepognjena na sredini z vidno prvo stranjo (naslovom); pharma kodi, ki izhajata iz sredine navodila, morata biti vidni!

■ - *ČrnaU/BlackU*

KRKA

Šifra/Article No.: 458541
Emb. mat./Article name.: NA./PL.ZALASTA ODT GB/IE
Dimenzije/Dimension: 148 ± 0,5 mm x 520 ± 0,8 mm
Material: papir tip B/Woodfree paper 50 g/m²
PhC št./PhC No.: 53714
Merilo/Measure: 1:1
Datum/Date: 25.11.2019
Izdelal/Prepared by: D. Primc
Pregledal/Checked by: N. Regina
Oddelek za oblikovanje/Packaging Design

130 mm ± 0,5 mm

smer branja kode/direction of reading PhC

148 mm ± 0,5 mm

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor immediately if you have:
- unusual movement (a common side effect that may affect up to 1 in 10 people) mainly of the face or tongue;
- blood clots in the veins (an uncommon side effect that may affect up to 1 in 100 people) especially in the legs (symptoms include swelling, pain, and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms seek medical advice immediately;
- a combination of fever, faster breathing, sweating, muscle stiffness and drowsiness or sleepiness (the frequency of this side effect cannot be estimated from the available data).

Very common side effects (may affect more than 1 in 10 people) include weight gain; sleepiness and increases in levels of prolactin in the blood. In the early stages of treatment, some people may feel dizzy or faint (with a slow heart rate), especially when getting up from a lying or sitting position. This will usually pass on its own but if it does not, tell your doctor.

Common side effects (may affect up to 1 in 10 people) include changes in the levels of some blood cells, circulating fats and early in treatment, temporary increases in liver enzymes; increases in the level of sugars in the blood and urine; increases in levels of uric acid and creatine phosphokinase in the blood; feeling more hungry; dizziness; restlessness; tremor; unusual movements (dyskinesias); constipation; dry mouth; rash; loss of strength; extreme tiredness; water retention leading to swelling of the hands, ankles or feet; fever; joint pain; and sexual dysfunctions such as decreased libido in males and females or erectile dysfunction in males.

Uncommon side effects (may affect up to 1 in 100 people) include hypersensitivity (e.g. swelling in the mouth and throat, itching, rash); diabetes or the worsening of diabetes, occasionally associated with ketoacidosis (ketones in the blood and urine) or coma; seizures, usually associated with a history of seizures (epilepsy); muscle stiffness or spasms (including eye movements); restless legs syndrome; problems with speech; stuttering; slow heart rate; sensitivity to sunlight; bleeding from the nose; abdominal distension; memory loss or forgetfulness; urinary incontinence; lack of ability to urinate; hair loss; absence or decrease in menstrual periods; and changes in breasts in males and females such as an abnormal production of breast milk or abnormal growth.

Rare side effects (may affect up to 1 in 1000 people) include lowering of normal body temperature; abnormal rhythms of the heart; sudden unexplained death; inflammation of the pancreas causing severe stomach pain, fever and sickness; liver disease appearing as yellowing of the skin and white parts of the eyes; muscle disease presenting as unexplained aches and pains; and prolonged and/or painful erection.

Very rare side effects include serious allergic reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS appears initially as flu-like symptoms with a rash on the face and then with an extended rash, high temperature, enlarged lymph nodes, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia).

While taking olanzapine, elderly patients with dementia may suffer from stroke, pneumonia, urinary incontinence, falls, extreme tiredness, visual hallucinations, a rise in body temperature, redness of the skin and have trouble walking. Some fatal cases have been reported in this particular group of patients.

In patients with Parkinson's disease Zalasta may worsen the symptoms.

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zalasta

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light and moisture. This medicine does not require any special temperature storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Zalasta contains
- The active substance is olanzapine. Each orodispersible tablet contains 5 mg, 7.5 mg, 10 mg, 15 mg or 20 mg olanzapine.
- The other ingredients are mannitol, microcrystalline cellulose, crospovidone, low-substituted hydroxypropylcellulose, aspartame, calcium silicate, magnesium stearate.
  See section 2 "Zalasta contains aspartame".

What Zalasta looks like and contents of the pack
Zalasta 5 mg, 7.5 mg, 10 mg, 15 mg and 20 mg orodispersible tablets are: round, slightly biconvex, yellow marbled tablets with possible individual spots.

Zalasta 5 mg, 7.5 mg, 10 mg, 15 mg and 20 mg orodispersible tablets: available in boxes of 14, 28, 35, 56 and 70 tablets in blisters.

Marketing Authorisation Holder
KRKA, d.d., Novo mesto, Šmarješka cesta 6,
8501 Novo mesto, Slovenia

Manufacturer
KRKA-POLSKA Sp. z o.o., ul. Równolegla 5,
02-235 Warszawa, Poland

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Ireland
KRKA Pharma Dublin, Ltd.
Tel: + 353 1 293 91 80

United Kingdom
Consilient Health (UK) Ltd.
Tel: + 44(0)203 751 1888

This leaflet was last revised in 06/2019.

Detailed information on this medicine is available on the European Medicines Agency web site:
http://www.ema.europa.eu

KRKA 458541

smer vlaken/direction on fibre

520 mm ± 0,8 mm

130 mm ± 0,5 mm

smer branja kode/direction of reading PhC