Package leaflet: Information for the patient

Arkolamyl 5 mg Orodispersible Tablets
Arkolamyl 10 mg Orodispersible Tablets
Arkolamyl 15 mg Orodispersible Tablets
Arkolamyl 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.

What is in this leaflet

1. What Arkolamyl is and what it is used for

Arkolamyl contains the active substance olanzapine. Olanzapine belongs to a group of medicines called antipsychotics and is used to treat the following mental health conditions:

- Schizophrenia, a condition with symptoms such as hearing, seeing or sensing things which are not there, mistaken beliefs, unusual suspiciousness, and becoming withdrawn. People with this condition may also feel depressed, anxious or tense.

- Moderate to severe manic episodes, a condition with symptoms of excitement or euphoria.

Arkolamyl 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 Arkolamyl

Do not take Arkolamyl
- If you are allergic 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, tongue or throat, difficulty breathing 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 taking Arkolamyl if:

- you are elderly with dementia as you may get serious side effects.
- you or someone in your family has a history of blood clots, as medicines like this have been associated with formation of blood clots.
- you have had a stroke or "mini" stroke (temporary symptoms of stroke)
- you have Parkinson's disease as your signs of illness may get worse
- you have an enlarged prostate problems
- you have a blocked intestine (paralytic ileus)
- you have problems with your liver or kidneys
- you have problems with your blood cells
- you have heart disease
- you have problems with the electrical activity of the heart
- you have low levels of potassium or magnesium in the blood
- you have diabetes
- you have a history of fits or seizures (epilepsy)
- you are a smoker

<u>During treatment</u>
If you experience a combination of a very high fever, faster breathing, excessive sweating, a change in mood, muscle stiffness, high blood pressure and drowsiness or sleepiness, speak to your doctor as your doctor may decide to discontinue Arkolamyl.

If you experience uncontrollable movements of the face or tongue, speak to your doctor as your doctor may consider to reduce the dose or discontinue Arkolamyl.

Weight gain has been seen in patients taking olanzapine. You and your doctor should check your weight regularly. Consider referral to a dietician or help with a diet plan if necessary.

Your doctor may also wish to perform blood tests before you start taking Arkolamyl and regularly during treatment to monitor blood sugar and fat levels.

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

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

Other medicines and Arkolamyl
Only take other medicines while you are on Arkolamyl if your doctor tells you that you can.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, especially any of the following:
- antidepressants or medicines taken for anxiety or to help you sleep (tranquillisers) as you may feel drowsy.
- medicines for Parkinson's disease.
- carbamazepine (an anti-epileptic and mood stabiliser).
- fluvoxamine (an antidepressant).
- ciprofloxacin (an antibiotic).
- activated charcoal. You should take this at least two hours before or after you take Arkolamyl.

Arkolamyl with alcohol

Do not drink any alcohol if you have been given Arkolamyl 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 or pharmacist for advice before taking this medicine. Your doctor will discuss with you whether you should take this medicine when pregnant.

You should not take this medicine when breast-feeding, as small amounts of Arkolamyl can pass into breast milk.

The following symptoms may occur in newborn babies, of mothers that have used Arkolamyl 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 or dizzy when you are given Arkolamyl. If this happens do not drive or operate any tools or machines. Tell your doctor.

Arkolamyl contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Arkolamyl

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

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

You should take your Arkolamyl orodispersible 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.

Arkolamyl orodispersible tablets break easily, so you should handle the tablets carefully. Do not handle the tablets with wet hands as the tablets may break up.

1. Hold the blister strip at the edges and separate one blister cell from the rest of the strip by gently tearing along the perforations around it.
2. Carefully peel off the backing.
3. Gently push the tablet out.
4. Put the tablet in your mouth. It will dissolve directly in your mouth, so that it can be easily swallowed.

You can also place the tablet in a full glass or cup of water, orange juice, apple juice, milk or coffee, and stir. With some drinks, the mixture may change colour and possibly become cloudy. Drink it straight away.

If you take more Arkolamyl than you should
Contact your doctor or hospital straight away. Show the doctor your pack of tablets.
Patients who have taken more Arkolamyl 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, inhaling fluid into the windpipe and lungs, often after being sick (aspiration), high blood pressure or low blood pressure, abnormal rhythms of the heart.

If you forget to take Arkolamyl
Take your tablets as soon as you remember. Do not take a double dose to make up for a forgotten dose.

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

If you suddenly stop taking Arkolamyl, symptoms such as sweating, difficulty sleeping, shaking, anxiety or feeling sick (nausea) and being sick (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.

4. Possible side effects

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

Immediately go to the nearest hospital emergency department or speak to your doctor if you have the following:

Common (may affect up to 1 in 10 people)
- an increase in the number of infections you get causing fever, severe chills, sore throat or mouth ulcers (these may indicate you have a low number of white blood cells).

Uncommon (may affect up to 1 in 100 people)
- uncontrolled movements of the mouth, tongue, cheeks or jaws, which may progress to the arms and legs (tardive dyskinesia).
- irregular heart rate.
- blood clots in the veins 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.
- allergic reactions such as a rash, itching or swelling of the face, lips, tongue or throat, difficulty breathing or shortness of breath.
- diabetes or the worsening of diabetes, occasionally associated with ketoacidosis (ketones in the blood and urine) or coma.

- difficulty urinating or emptying the bladder.
- seizures (usually associated with a history of seizures (epilepsy)).

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

- a combination of a very high fever, faster breathing, excessive sweating, change in mood, muscle stiffness, high blood pressure and drowsiness or sleepiness.
- shivering, cold or pale skin (these may be signs that your body temperature is lower than normal).
- a dangerously fast heart beat.
- severe stomach pain which may radiate to your back (this may be a sign of problems with your pancreas).
- yellowing of your skin or whites of your eyes, dark urine, pale stools, tiredness, fever, nausea, weakness, drowsiness and abdominal pain (these may be signs of problems with your liver).
- breakdown of muscle, causing muscle pain, weakness or tenderness accompanied by dark urine (rhabdomyolysis).

Not known (cannot be estimated from the available data)

- 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). These may be signs of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).

Other side effects include:

Very common (may affect more than 1 in 10 people)

- weight gain.
- sleepiness.
- increases in the levels of prolactin in the blood which can be seen in a blood test.
- 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 (may affect up to 1 in 10 people)

- changes in the levels of some white blood cells, circulating fats and early in treatment, temporary increases in liver enzymes which would be seen in a blood test.
- increases in the level of sugars in the blood and urine, which would be seen in a blood or urine test.
- increases in levels of uric acid and creatine phosphokinase in the blood, which would be seen in a blood test.
- feeling more hungry.
- dizziness.
- restlessness.
- tremor, rigid posture, slow movement, and a shuffling, unbalanced walk (Parkinsonism).
- unusual movements (dyskinesias).
- constipation.
- dry mouth.
- rash.
- unusual weakness.
- extreme tiredness.

- water retention leading to swelling of the hands, ankles or feet.
- decreased sex drive in males and females or problems getting or maintaining an erection in males
- fever.
- joint pain.

Uncommon (may affect up to 1 in 100 people)
- uncontrollable muscle stiffness or spasms affecting the head (including eye movements), neck or body.
- restless legs syndrome.
- problems with speech.
- slow heart rate.
- increase in sensitivity of skin to sunlight.
- bleeding from the nose.
- bloating feeling in your stomach.
- memory loss or forgetfulness.
- inability to control urination; difficulty in starting to urinate or maintaining the flow.
- hair loss.
- absence or decrease in menstrual periods.
- increase in breasts size in males or females
- abnormal production of breast milk in females.
- increase in bilirubin levels in the blood seen in a blood test.

Rare (may affect up to 1 in 1000 people)
- sudden unexplained death.
- signs of withdrawal such as sweating, difficulty sleeping, shaking, anxiety, feeling sick (nausea) or being sick (vomiting).
- unexplained bruising and bleeding more easily or for longer than usual.
- prolonged and/or painful erection.

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 Arkolamyl may worsen the symptoms.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Arkolamyl

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 carton and blister after “EXP”. The expiry date refers to the last day of that month**.**

Store in the original package in order to protect from light and moisture.

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 protect the environment.

6. Contents of the pack and other information

What Arkolamyl contains

- The active substance is olanzapine. Each Arkolamyl orodispersible tablet contains 5 mg, 10 mg, 15 mg or 20 mg of the active substance.
- The other ingredients are crospovidone, lactose monohydrate (see section 2 "Arkolamyl contains lactose"), colloidal anhydrous silica, hydroxypropylcellulose, mint flavour (consisting of: mint oil, terpeneless mint oil, eucalyptol, menthone, isomenthone, methylene acetate, menthol), talc and magnesium stearate.

What Arkolamyl looks like and contents of the pack

Arkolamyl 5 mg orodispersible tablets are yellow, round with two sides that curve out.
Arkolamyl 10 mg orodispersible tablets are yellow, round and flat.
Arkolamyl 15 mg orodispersible tablets are yellow, round with two sides that curve out.
Arkolamyl 20 mg are yellow, round and flat orodispersible tablets. Orodispersible tablet is the technical name for a tablet which dissolves directly in your mouth, so that it can be easily swallowed.

Blisters:
Arkolamyl 5 mg, 10 mg, 15 mg and 20 mg are available in cartons containing:

10, 28, 30, 56, 60, 70, 84, 90, 98, 100, 112 orodispersible tablets

Unit dose blisters:
Arkolamyl 5 mg, 10 mg, 15 mg and 20 mg are available in cartons containing 28 x 1 orodispersible tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

McDermott Laboratories Limited t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

Manufacturers

PHARMATHEN S.A., Dervenakion 6, Pallini 15351, Attikis Greece
McDermott Laboratories Limited t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark	Arkolamyl
Norway	Arkolamyl
Sweden	Arkolamyl munsönderfallande tablett 5mg, 10mg, 15mg and 20mg

United Kingdom	Arkolamyl 5mg, 10mg, 15mg and 20 mg Orodispersible tablets
France	Olanzapine Mylan Generiques 5mg, 10mg, 15mg and 20mg, comprimé orodispersible
Ireland	Arkolamyl 5mg, 10mg, 15mg and 20 mg orodispersible tablets
Italy	Arkolamyl

This leaflet was last revised in 01/2017