

PACKAGE LEAFLET

Package leaflet: Information for the user

Delmosart PR 18 mg prolonged-release tablets
Delmosart PR 27 mg prolonged-release tablets
Delmosart PR 36 mg prolonged-release tablets
Delmosart PR 54 mg prolonged-release tablets

Methylphenidate hydrochloride

Read all of this leaflet carefully before you or your child starts 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 or your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours or your child's ones.
- If you or your child 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 Delmosart PR is and what it is used for**
2. **What you need to know before you or your child take Delmosart PR**
3. **How to take Delmosart PR**
4. **Possible side effects**
5. **How to store Delmosart PR**
6. **Contents of the pack and other information**

1. **What Delmosart PR is and what it is used for**

What it is used for

Delmosart PR is used to treat 'attention deficit hyperactivity disorder' (ADHD).

- it is used in children and young people between the ages of 6 and 18.
- it is used only after trying treatments which do not involve medicines such as counselling and behavioural therapy.

Delmosart PR is not for use as a treatment for ADHD in children under 6 years of age or for initiation of treatment in adults. When treatment was started at a younger age, it might be appropriate to continue taking Delmosart PR when you become an adult. Your doctor will advise you about this.

How it works

Delmosart PR improves the activity of certain parts of the brain which are under-active. The medicine can help improve attention (attention span), concentration and reduce impulsive behaviour.

The medicine is given as part of a treatment programme, which usually includes:

- psychological
- educational and
- social therapy.

It is prescribed only by doctors who have experience in children or young people's behaviour problems. Although there is no cure for ADHD, it can be managed using treatment programmes.

About ADHD

Children and young people with ADHD find it:

- hard to sit still and
- hard to concentrate.

It is not their fault that they cannot do these things.

Many children and young people struggle to do these things. However, with ADHD they can cause problems with everyday life. Children and young people with ADHD may have difficulty learning and doing homework. They find it hard to behave well at home, at school or in other places. ADHD does not affect the intelligence of a child or young person.

2. What you need to know before you or your child take Delmosart PR

Do not take Delmosart PR if you or your child:

- are allergic to methylphenidate or any of the other ingredients of this medicine (listed in section 6)
- have a thyroid problem
- have increased pressure in your eye (glaucoma)
- have a tumour of your adrenal gland (phaeochromocytoma)
- have an eating problem when you do not feel hungry or want to eat - such as 'anorexia nervosa'
- have very high blood pressure or narrowing of the blood vessels, which can cause pain in the arms and legs
- have ever had heart problems - such as a heart attack, uneven heartbeat, pain and discomfort in the chest, heart failure, heart disease or were born with a heart problem
- have had a problem with the blood vessels in your brain - such as a stroke, swelling and weakening of part of a blood vessel (aneurysm), narrow or blocked blood vessels, or inflammation of the blood vessels (vasculitis)
- are currently taking or have taken within the last 14 days an antidepressant (known as a monoamine oxidase inhibitor)- see 'Other medicines and Delmosart PR'
- have mental health problems such as:
 - a 'psychopathic' or 'borderline personality' problem
 - abnormal thoughts or visions or an illness called 'schizophrenia'
 - signs of a severe mood problem like:
 - feeling like killing yourself
 - severe depression, where you feel very sad, worthless and hopeless
 - mania, where you feel unusually excitable, over-active, and un-inhibited.

Do not take methylphenidate if any of the above apply to you or your child. If you are not sure, talk to your doctor or pharmacist before you or your child take methylphenidate. This is because methylphenidate can make these problems worse.

Warnings and precautions

Talk to your doctor before taking Delmosart PR if you or your child:

- have liver or kidney problems
- have a problem with swallowing or swallowing whole tablets
- have a narrowing or blockage of your gut or food-pipe
- have had fits (seizures, convulsions, epilepsy) or any abnormal brain scans (EEGs)
- have ever abused or been dependent on alcohol, prescription medicines or street drugs
- are a girl and have started your periods (see the 'Pregnancy, breast-feeding and contraception' section below)
- have hard-to-control, repeated twitching of any parts of the body or you repeat sounds and words
- have high blood pressure
- have a heart problem which is not in the 'Do not take' section above
- have a mental health problem which is not in the 'Do not take' section above.

Other mental health problems include:

- mood swings (from being manic to being depressed - called 'bipolar disorder')
- starting to be aggressive or hostile, or your aggression gets worse
- seeing, hearing or feeling things that are not there (hallucinations)
- believing things that are not true (delusions)
- feeling unusually suspicious (paranoia)
- feeling agitated, anxious or tense

- feeling depressed or guilty.

Tell your doctor or pharmacist if any of the above apply to you or your child before starting treatment. This is because methylphenidate can make these problems worse. Your doctor will want to monitor how the medicine affects you or your child.

During treatment, boys and adolescents may unexpectedly experience prolonged erections. This may be painful and can occur at any time. It is important to contact your doctor straight away if your erection lasts for longer than 2 hours, particularly if this is painful.

Checks that your doctor will make before you or your child start taking methylphenidate

These checks are to decide if methylphenidate is the correct medicine for you or your child. Your doctor will talk to you about:

- any other medicines you or your child are taking
- whether there is any family history of sudden unexplained death
- any other medical problems (such as heart problems) you or your family may have
- how you or your child are feeling, such as feeling high or low, having strange thoughts or if you have had any of these feelings in the past
- whether there is a family history of ‘tics’ (hard-to-control, repeated twitching of any parts of the body or repeating sounds and words)
- any mental health or behaviour problems you or other family members have ever had.

Your doctor will discuss whether you or your child are at risk of having mood swings (from being manic to being depressed - called ‘bipolar disorder’). They will check your mental health history, and check if any of your family have a history of suicide, bipolar disorder or depression.

It is important that you provide as much information as you can. This will help your doctor decide if methylphenidate is the correct medicine for you or your child. Your doctor may decide that other medical tests are needed before you or your child start taking this medicine.

Other medicines and Delmosart PR

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

Do not take methylphenidate if you or your child:

- are taking a medicine called a ‘monoamine oxidase inhibitor’ (MAOI) used for depression, or have taken an MAOI in the last 14 days. Taking an MAOI with methylphenidate may cause a sudden increase in your blood pressure.

If you or your child are taking other medicines, methylphenidate may affect how well they work or may cause side effects. If you or your child are taking any of the following medicines, check with your doctor or pharmacist before taking methylphenidate:

- other medicines for depression
- medicines for severe mental health problems
- medicines for epilepsy
- medicines used to reduce or increase blood pressure
- some cough and cold remedies which contain medicines that can affect blood pressure. It is important to check with your pharmacist when you buy any of these products
- medicines that thin the blood to prevent blood clots.

If you are in any doubt about whether any medicines you or your child are taking are included in the list above, ask your doctor or pharmacist before taking methylphenidate.

Please tell you doctor or pharmacist if you or your child are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Having an operation

Tell your doctor if you or your child are going to have an operation. You should not take methylphenidate on the day of your surgery if a certain type of anaesthetic is used. This is because there is a chance of a sudden rise in blood pressure during the operation.

Drug testing/anti-doping testing

This medicine may give a positive result when testing for drug use. This includes testing used in sport.

Delmosart PR with alcohol

Do not drink alcohol while taking this medicine. Alcohol may make the side effects of this medicine worse. Remember that some foods and medicines contain alcohol.

Pregnancy, breast-feeding and fertility

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.

. Available data do not suggest an increased risk of overall birth defects, whilst a small increase in the risk of malformations of the heart when used during the first three months of pregnancy could not be ruled out. Your doctor will be able to give you more information about this risk.

Tell your doctor or pharmacist before using methylphenidate if you or your child are:

- having sex. Your doctor will discuss contraception with you
- pregnant or think you may be pregnant. Your doctor will decide whether you should take methylphenidate.
- breast-feeding or planning to breast-feed. It is possible that methylphenidate is passed into human breast milk. Therefore, your doctor will decide whether you should breast-feed while taking methylphenidate.

Driving and using machines

You or your child may feel dizzy, have problems focussing or have blurred vision when taking methylphenidate. If these happen it may be dangerous to do things such as drive, use machines, ride a bike or horse or climb trees.

Delmosart PR contains lactose

This medicine contains lactose. If you or your child 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 Delmosart PR

How much to take

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

- your doctor will usually start treatment with a low dose and increase it gradually as required.
- the maximum daily dose is 54 mg.
- Oral use
- Delmosart PR should be taken once each day in the morning with a glass of water.

The tablet should be swallowed whole and not chewed, broken, divided or crushed. The tablet may be taken with or without food.

If you or your child do not feel better after 1 month of treatment

If you or your child do not feel better, tell your doctor. They may decide you need a different treatment.

Things your doctor will do when you are on treatment

Your doctor will do some tests

- before you start - to make sure that Delmosart PR is safe and will be of benefit.

- after you start - they will be done at least every 6 months, but possibly more often. They will also be done when the dose is changed.
- these tests will include:
 - checking your appetite
 - measuring height and weight
 - measuring blood pressure and heart rate
 - checking whether you have any problems with your mood, state of mind or any other unusual feelings. Or if these have got worse while taking Delmosart PR.

Long-term treatment

Delmosart PR does not need to be taken forever. If you or your child take Delmosart PR for more than a year, your doctor should stop treatment for a short time, this may happen during a school holiday. This will show if the medicine is still needed.

Not using Delmosart PR properly

If Delmosart PR is not used properly, this may cause abnormal behaviour. It may also mean that you start to depend on the medicine. Tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines or street drugs.

This medicine is only for you. Do not give this medicine to anyone else, even if their symptoms seem similar.

If you take more Delmosart PR than you should

If you or your child take too much medicine, talk to a doctor or call an ambulance straight away. Tell them how much has been taken.

Signs of overdose may include: being sick, feeling agitated, shaking, increased uncontrolled movements, muscle twitching, fits (may be followed by coma), feeling very happy, being confused, seeing, feeling or hearing things that are not real (hallucinations), sweating, flushing, headache, high fever, changes in heart beat (slow, fast or uneven), high blood pressure, dilated pupils and dry nose and mouth.

If you or your child forget to take Delmosart PR

Do not take a double dose to make up for a forgotten dose. If you forget a dose, wait until it is time for the next dose.

If you stop taking Delmosart PR

If you or your child suddenly stop taking this medicine, the ADHD symptoms may come back or unwanted effects such as depression may appear. Your doctor may want to gradually reduce the amount of medicine taken each day, before stopping it completely. Talk to your doctor before stopping Delmosart PR.

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. Although some people get side effects, most people find that methylphenidate helps them. Your doctor will talk to you about these side effects.

Some side effects could be serious. If you or your child has any of the side effects below, see a doctor straight away:

Common (may affect up to 1 in 10 people)

- uneven heartbeat (palpitations)
- mood changes or mood swings or changes in personality

Uncommon (may affect up to 1 in 100 people)

- thinking about or feeling like killing yourself
- seeing, feeling, or hearing things that are not real, these are signs of psychosis

- uncontrolled speech and body movements (Tourette's)
- signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing

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

- feeling unusually excited, over-active and un-inhibited (mania)

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

- heart attack
- sudden death
- suicidal attempt
- fits (seizures, convulsions epilepsy)
- skin peeling or purplish red patches
- inflammation or blocked arteries in the brain
- muscle spasms which you cannot control affecting your eyes, head, neck, body and nervous system - due to a temporary lack of blood supply to the brain
- decrease in number of blood cells (red cells, white cells and platelets) which can make you more likely to get infections, and make you bleed and bruise more easily
- a sudden increase in body temperature, very high blood pressure and severe convulsions ('Neuroleptic Malignant Syndrome'). It is not certain that this side effect is caused by methylphenidate or other medicines that may be taken in combination with methylphenidate.

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

- unwanted thoughts that keep coming back
- unexplained fainting, chest pain, shortness of breath (these can be signs of heart problems)
- paralysis or problems with movement and vision, difficulties in speech (these can be signs of problems with the blood vessels in your brain)
- prolonged erections, sometimes painful, or an increased number of erections

If you or your child has any of the side effects above, see a doctor straight away.

Other side effects include the following, if they get serious, please tell your doctor or pharmacist:

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

- headache
- feeling nervous
- not being able to sleep.

Common (may affect up to 1 in 10 people)

- joint pain
- blurred vision
- tension headache
- dry mouth, thirst
- trouble falling asleep
- high temperature (fever)
- decreased interest in sex
- unusual hair loss or thinning
- muscle tightness, muscle cramps
- loss of appetite or decreased appetite
- inability to develop or maintain an erection
- itching, rash or raised red itchy rashes (hives)
- feeling unusually sleepy or drowsy, feeling tired
- excessive teeth grinding (bruxism), feeling of panic
- tingling feeling, prickling, or numbness of the skin
- increased alanine aminotransferase (liver enzyme) level in your blood

- cough, sore throat or nose and throat irritation; upper respiratory tract infection; sinus infection
- high blood pressure, fast heart beat (tachycardia)
- dizziness (vertigo), feeling weak, movements which you cannot control, being unusually active
- feeling aggressive, agitated, anxious, depressed, irritable, tense, jittery and abnormal behaviour
- upset stomach or indigestion, stomach pain, diarrhoea, feeling sick, stomach discomfort and being sick.

Uncommon (may affect up to 1 in 100 people)

- dry eyes
- constipation
- chest discomfort
- blood in the urine
- listlessness
- shaking or trembling
- increased need to pass urine
- muscle pain, muscle twitching
- shortness of breath or chest pain
- feeling hot
- increases in liver test results (seen in a blood test)
- anger, feeling restless or tearful, talking too much, excessive awareness of surroundings, problems sleeping.

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

- feeling disorientated or confused
- trouble seeing or double vision
- swelling of the breasts in men
- excessive sweating, redness of the skin, red raised skin rash.

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

- muscle cramps
- small red marks on the skin
- abnormal liver function including liver failure and coma
- changes in test results – including liver and blood tests
- abnormal thinking, lack of feeling or emotion, doing things over and over again, being obsessed with one thing
- fingers and toes feeling numb, tingling and changing colour (from white to blue, then red) when cold ('Raynaud's phenomenon').

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

- migraine
- dilated pupils
- inability to control the excretion of urine (incontinence)
- spasm of the jaw muscles that makes it difficult to open the mouth (trismus)
- very high fever
- slow, fast or extra heart beats
- a major fit ('grand mal convulsions')
- believing things that are not true
- severe stomach pain, often with feeling and being sick.

Effects on growth

When used for more than a year, methylphenidate may cause reduced growth in some children. This affects less than 1 in 10 children.

- there may be lack of weight gain or height growth.

- your doctor will carefully watch your height and weight, as well as how well you are eating.
- if you are not growing as expected, then your treatment with methylphenidate may be stopped for a short time.

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 HPRAs 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 Delmosart PR

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 the label after 'EXP'. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Shelf life after first opening the bottle:

18 mg tablets: 3 months

27 mg tablets: 6 months

36 mg tablets: 6 months

54 mg tablets: 6 months

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 Delmosart PR contains

The active substance is methylphenidate hydrochloride

Delmosart PR 18mg: Each prolonged-release tablet contains 18mg of methylphenidate hydrochloride equivalent to 15.6 mg of methylphenidate.

Delmosart PR 27mg: Each prolonged-release tablet contains 27mg of methylphenidate hydrochloride equivalent to 23.3 mg of methylphenidate.

Delmosart PR 36mg: Each prolonged-release tablet contains 36mg of methylphenidate hydrochloride equivalent to 31.1 mg of methylphenidate.

Delmosart PR 54mg: Each prolonged-release tablet contains 54mg of methylphenidate hydrochloride equivalent to 46.7 mg of methylphenidate.

The other ingredients are:

Tablet Core:

Lactose monohydrate, hypromellose, silica (colloidal anhydrous), magnesium stearate, fumaric acid, methacrylic acid–methyl methacrylate copolymer (1:1), methacrylic acid–methyl methacrylate copolymer (1:2), triethyl citrate, talc.

Tablet coating:

18 mg Tablets: Polyvinyl alcohol (part hydrolysed), macrogol (3350), talc, titanium dioxide (E171), iron oxide yellow (E172), iron oxide red (E172).

27 mg Tablets: Polyvinyl alcohol (part hydrolysed), macrogol (3350), talc, titanium dioxide (E171), iron oxide yellow (E172), Indigo carmine aluminium lake (E132), iron oxide black (E172).

36 mg Tablets: Polyvinyl alcohol (part hydrolysed), macrogol (3350), talc, titanium dioxide (E171).

54 mg Tablets: Polyvinyl alcohol (part hydrolysed), macrogol (3350), talc, titanium dioxide (E171), iron oxide red (E172).

Printing ink:

Shellac glaze, iron oxide black (E172), propylene glycol.

What Delmosart PR looks like and contents of the pack

18 mg Tablet: Capsule-shaped, biconvex, yellow tablet, 6.6 mm x 11.9 mm, with “2392” printed on one side in black ink.

27 mg Tablet: Capsule-shaped, biconvex, grey tablet, 6.7 mm x 12.0 mm, with “2393” printed on one side in black ink.

36 mg Tablet: Capsule-shaped, biconvex, white tablet, 6.7 mm x 12.0 mm, with “2394” printed on one side in black ink.

54 mg Tablet: Capsule-shaped, biconvex, red-brown tablet, 6.8 mm x 12.0 mm, with “2395” printed on one side in black ink.

Delmosart PR is available in bottles with child-resistant closure, with silica gel desiccant integrated into the closure, containing 28, 30 or 90 prolonged-release tablets (18 mg tablets) or 28, 30 or 100 prolonged-release tablets (27 mg, 36 mg and 54 mg tablets). Not all pack sizes may be marketed.

Marketing Authorisation Holder

Actavis Group PTC ehf
Reykjavíkurvegi 76-78
220 Hafnarfjörður
Iceland

Manufacturer

Balkanpharma – Dupnista AD
3 Samokovsko Shosse Str.,
Dupnista 2600
Bulgaria

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

Ireland	Delmosart PR 18 mg, 27 mg, 36 mg, 54 mg prolonged-release tablets
United Kingdom	Delmosart 18 mg, 27 mg, 36 mg, 54 mg Prolonged-release tablets

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