

PACKAGE LEAFLET

Package leaflet: Information for the patient

Medanef 5 mg Tablets

Medanef 10 mg Tablets

Medanef 20 mg 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.
- 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 Medanef is and what it is used for
2. What you need to know before you or your child takes Medanef
3. How to take Medanef
4. Possible side effects
5. How to store Medanef
6. Contents of the pack and other information

1. What Medanef is and what it is used for

Medanef contains the active substance methylphenidate.

Medanef 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

Medanef is not for use as a treatment for ADHD in children under 6 years of age or in adults. It is not known if it is safe or of benefit in these people.

How it works

Medanef improves the activity of certain parts of the brain which are underactive. 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

Medanef must only be initiated by, and used under the supervision of, a specialist in childhood/and or adolescent behavioural disorders. 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
- 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 takes Medanef

Do not take Medanef 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 the eye (glaucoma)
- have a tumour of the adrenal gland (phaeochromocytoma)
- have an eating problem when you or your child 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 or 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 Medanef ")
- have or have had 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 uninhibited

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Medanef if you or your child:

- have liver or kidney problems
- have had fits (seizures, convulsions, epilepsy) or any abnormal brain scans (EEG)
- is female and have started having periods (see the 'Pregnancy and breast-feeding' section below)
- have ever abused or been dependent on alcohol, prescription medicines or street drugs
- have hard-to-control repeated twitching of any parts of the body or you repeat sounds and words (tics)
- have high blood pressure
- have a heart problem which is not mentioned in the section 'Do not take Medanef if you or your child:'
- have a mental health problem which is not mentioned in the section 'Do not take Medanef if you or your child:'

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
- 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 applies 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.

If you or your child develop blurred vision or other visual disturbances contact your doctor. Your doctor may consider discontinuation of Medanef.

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

These checks are to decide if Medanef 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, your child or your family may have,
- how you or your child are feeling, such as feeling high or low, having strange thoughts or if you or your child 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 your child or other family members have or 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'). Your doctor will check your or your child's mental health history, and check if any of your family has 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.

During treatment

If you or your child take this medicine for longer than 12 months your doctor may want to monitor heart function, height, weight, appetite or mental health and may wish you or your child to stop taking Medanef to check if treatment is still necessary.

Tell your doctor if you or your child get any of the following:

- uncontrolled speech or body movements,
- any changes or worsening of your mood or behaviour,
- difficulty breathing,
- shortness of breath,
- chest pain or palpitations (a fast heart beat which feels like a thumping in the chest), as your doctor may decide to stop treatment. Your doctor may check for signs of these at every change of dose, every 6 months or at every visit.

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 two hours, particularly if this is painful.

Other medicines and Medanef

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

Do not take Medanef if you or your child:

- are taking a medicine called a 'monoamine oxidase inhibitor' (MAOI) used for depression such as phenelzine or isocarboxazid, or have taken a MAOI in the last 14 days. Taking a MAOI with methylphenidate may cause a sudden increase in your or your child's 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 Medanef:

- other medicines for depression such as tricyclic antidepressants (e.g. amitriptyline, clomipramine) or selective serotonin reuptake inhibitors (SSRIs) (e.g. citalopram, fluoxetine),
- medicines for severe mental health problems such as amisulpride, risperidone, lithium, haloperidol,
- DOPA, a medicine used for Parkinson's disease,
- medicines for epilepsy such as phenobarbital, phenytoin, primidone,
- medicines used to reduce or increase blood pressure such as clonidine,
- 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 such as coumarin or warfarin.

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 for advice before taking Medanef

Having an operation

Tell your doctor if you or your child are going to have an operation. Medanef should not be taken on the day of a 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.

Medanef with food and alcohol

Taking Medanef with food may help relieve stomach pains, feeling sick or vomiting.
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 and breast-feeding

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. Methylphenidate is present in breast milk. Tell your doctor or pharmacist before using methylphenidate if you or your daughter:

- are sexually active. Your doctor will discuss contraception
- are pregnant or might be pregnant. Your doctor will decide whether methylphenidate should be taken

- are 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 or your daughter should breast-feed while taking methylphenidate.

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.

Driving and using machines

You may feel dizzy, drowsy, have problems focusing or have blurred or double vision when taking methylphenidate. If these happen, do not drive, use machines, ride a bike or horse or climb trees.

3. How to take Medanef

Before you or your child start treatment, at every change of dose and then at least every 6 months or at every visit your doctor will conduct various tests to make sure that methylphenidate is still acceptably safe and beneficial. These will include:

- measuring blood pressure and heart rate and recording these on a chart
- measuring height, weight and appetite recording these on a chart
- assessing psychiatric symptoms (see section 2 ‘Warnings and precautions’)

How much to take

You or your child should 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 usually start treatment with a low dose and increase it gradually as required
- the maximum recommended daily dose is 60 mg
- you or your child should take Medanef once or twice daily (e.g. at breakfast and/or at lunchtime), with a glass of water
- the score line is only there to help you break the tablet if you have difficulty swallowing it whole.
[10 mg/20 mg only]

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 a different treatment is needed.

Long-term treatment

Medanef does not need to be taken forever. If you or your child takes Medanef 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 Medanef properly

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

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

If you or your child take more Medanef than you or your child should

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

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, muscle weakness, spasms and pain, fever, red-brown urine which could be possible signs of abnormal breakdown of muscles (rhabdomyolysis).

If you or your child forget to take Medanef

Do not take a double dose to make up for a forgotten dose. If you or your child have forgotten a dose, wait until the next dose.

If you or your child stop taking Medanef

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 Medanef.

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 very serious. If you or your child have any of the side effects below, go immediately to the nearest hospital emergency department:

Common (may affect up to 1 in 10 people)

- uneven heartbeats (arrhythmia) or racing heartbeats that feel like thumping inside your chest (palpitations)
- changes in blood pressure or number of heart beats, usually an increase

Uncommon (may affect up to 1 in 100 people)

- thinking about or feeling like killing yourself
- signs of allergic reaction such as rash, itching, blistering, scaling, redness, peeling of the skin or hives, swelling of the face, ear, lips, tongue or throat causing difficulty breathing, shortness of breath or wheezing

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

- heavy or pressing sensation on your chest with chest pain and shortness of breath on exercise (these may be signs you have angina)

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

- sudden chest pain which may spread to the neck or arm, with a shortness of breath and clammy feeling. These may be signs of a heart attack
- sudden death
- attempted suicide (including completed suicide)
- fits
- muscle spasms which cannot be controlled affecting your eyes, head, neck, body and nervous system. This may be due to a temporary lack of blood supply to the brain
- sudden collapse, numbness or weakness in the arms or legs, headache, dizziness or confusion, disturbances in vision, difficulty swallowing, slurred, mixed up or loss of speech. These may be signs of a stroke or mini stroke caused by a clot or bleed affecting blood supply to part of the brain
- decrease in number of white blood cells which can make you more likely to get infections that you may see as fevers, severe chills or a sore throat

- yellowing of the skin and eyes, dark urine, tiredness, fever, feeling sick (nausea), weakness, drowsiness and stomach pain. These may be signs of serious liver problems
- forgetfulness, poor judgement, a musty or sweet smelling breath, changes in sleep, worsening of hand movements or shaking of hands or arms. These are signs of problems with the brain caused by the liver not working
- a sudden increase in body temperature, very high blood pressure or severe convulsions ('Neuroleptic Malignant Syndrome'). It is not certain that this side effect is caused by methylphenidate or other drugs that may be taken in combination with methylphenidate

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

- a decrease in the number of other types of blood cell such as red blood cells or platelets which can cause tiredness, short of breath, pale skin or cause unexplained bruising or bleeding for longer than normal

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

Common (may affect up to 1 in 10 people)

- feeling aggressive, agitated, anxious, depressed or have a change in behaviour
- weight loss
- slower growth. You or your child, on long term treatment, may grow slower in comparison to others of the same sex and age (growth retardation)

Uncommon (may affect up to 1 in 100 people)

- feeling, or hearing things that are not real or believing things that are not true. These are signs of psychosis
- uncontrolled speech or body movements. If you already have these signs or Tourette's syndrome, they may get worse
- mood changes or mood swings or changes in personality
- dry eye

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

- feeling unusually excited, over-active or un-inhibited (mania)
- Obsessive-compulsive disorder (OCD) (including irresistible urge to pull out body hair, skin picking, having repeated unwanted thoughts, feelings, images or urges in your mind (obsessive thoughts), performing repeated behaviours or mental rituals (compulsions))

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

- difficulty thinking or not thinking clearly
- prolonged erections, sometimes painful, or an increased number of erections
- increased pressure in the eye
- eye diseases which may cause decreased vision due to damage to the eye nerve (glaucoma)

Other possible side effects include the following:

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

- headache
- feeling sick (nausea)
- dry mouth
- feeling nervous
- not being able to sleep
- decreased appetite

Common (may affect up to 1 in 10 people)

- joint pain
- high temperature (fever)
- cold hands or feet
- shortness of breath
- unusual hair loss or thinning
- tiredness
- thirst
- feeling unusually sleepy or drowsy
- loss of appetite (anorexia)
- cough, sore throat or blocked, stuffy or runny nose and throat irritation
- toothache
- excessive teeth grinding (bruxism)
- high blood pressure
- dizziness, movements which you cannot control, being unusually active
- shaking or trembling
- feeling stressed, irritable, restless
- nervousness
- excessive sweating
- unstable, quickly changing emotions
- panic attacks
- problems sleeping
- problems with sex drive
- indigestion
- stomach pain, diarrhoea, stomach discomfort and being sick (vomiting). These usually occur at the beginning of treatment and may be reduced by taking the medicine with food

Uncommon (may affect up to 1 in 100 people)

- constipation
- blood in the urine
- heart murmur
- unable to sit or stand still
- blistering, scaling, redness or peeling of the skin
- double or blurred vision
- tense muscles, muscle pain or muscle twitching
- chest pain
- increases in liver test results which can be seen in a blood test
- anger, feeling tense, feeling tearful, excessive awareness of surroundings

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

- changes in sex drive
- feeling disorientated
- dilated pupils, difficulty focussing your sight
- swelling of the breasts in men

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

- muscle cramps
- lack of feeling, emotion, interest or concern
- repeating behaviours
- over focusing
- changes in your blood as seen in a test, such as an increase in an enzyme called alkaline phosphatase or bilirubin, a low number of platelets or an abnormal white blood cell level

- fingers and toes feeling cold, 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
- chest discomfort
- confusion
- very high fever
- slow or extra heart beats
- dependence on this medicine
- problems getting or maintaining an erection
- inability to control the excretion of urine (incontinence)
- spasm of the jaw muscles that makes it difficult to open the mouth (trismus)
- stuttering
- nosebleed

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 [the national reporting system listed in Appendix V*](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Medanef

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 box after "EXP". The expiry date refers to the last day of that month.

Do not store above 30°C.

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 Medanef contains

Medanef 5 mg tablets

The active substance is methylphenidate hydrochloride. Each tablet contains 5 mg methylphenidate hydrochloride.

Medanef 10 mg tablets

The active substance is methylphenidate hydrochloride. Each tablet contains 10 mg methylphenidate hydrochloride.

Medanef 20 mg tablets

The active substance is methylphenidate hydrochloride. Each tablet contains 20 mg methylphenidate hydrochloride.

The other ingredients are microcrystalline cellulose, maize starch, magnesium stearate and calcium hydrogen phosphate dihydrate.

What Medanef looks like and contents of the pack

Medanef 5 mg tablets are white, round, flat, tablets marked with “RU” on one side and “5” on the other side.

Medanef 10 mg tablets are white, round, flat, scored tablets marked with “RU 10” on one side.

Medanef 20 mg tablets are white, round, flat, scored tablets marked with “RU 20” on one side.

Medanef is available in blisters of :

5 mg: 20, 30, 60 and 100 tablets.

10 mg: 20, 30, 60, 100 and 200 tablets.

20 mg: 20, 30 and 60 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

Laboratorios Rubió, S.A., Industria, 29, Pol. Ind. Comte de Sert, 08755 Castellbisbal, Barcelona, Spain.

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

Belgium	Methylphenidate Viatris 5 mg, 10 mg, 20 mg tabletten
Denmark	Medanef 5 mg, 10 mg , 20 mg tabletter
The Netherlands	Methylfenidaat HCl Viatris 5 mg, 10 mg tabletten
Norway	Medanef 5 mg, 10 mg, 20 mg tabletter
Sweden	Medanef 5 mg, 10 mg, 20 mg Tablets
United Kingdom	Methylphenidate Hydrochloride 5 mg, 10 mg, 20 mg Tablets

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