Package leaflet: Information for the user

Exattent XL 10 mg modified-release hard capsules
Exattent XL 20 mg modified-release hard capsules
Exattent XL 30 mg modified-release hard capsules
Exattent XL 40 mg modified-release hard capsules
Exattent XL 50 mg modified-release hard capsules
Exattent XL 60 mg modified-release hard capsules

methylphenidate hydrochloride

The name of your medicine is Exattent XL, it contains the active substance 'methylphenidate hydrochloride'. The name methylphenidate will also be used in this leaflet.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

This medicine is used to treat ADHD:
- The full name for ADHD is 'Attention Deficit Hyperactivity Disorder'.
- The medicine helps with your brain activity. It can help improve your attention, help you concentrate, and make you less impulsive.
- You need to have other treatments for ADHD as well as this medicine.

Read Section 1 for more information.

Before you take this medicine, talk to your doctor if:
- You have heart, circulation, or mental health problems - you may not be able to take this medicine.
- You are taking any other medicines - this is because methylphenidate can affect how other medicines work.

Read Section 2 for more information.

While taking this medicine:
- See your doctor regularly. This is because your doctor will want to check how the medicine is working.
- Do not stop taking the medicine without first talking to your doctor.
- Your doctor may stop your medicine to see if it is still needed, if you take it for more than a year.
- The most common side effects are feeling nervous, not being able to sleep or having a headache.

Read Sections 3 and 4 for more information.

Talk to your doctor straight away if any of the following happen:
- Your mood and how you feel changes.
- You feel any problems with your heart.

Read Section 4 for more information.

The rest of this leaflet includes more detail and other important information on the safe and effective use of this medicine.
- 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.

The leaflet has been written in sections:
- Sections 1 to 6 are for parents and carers (sometimes called 'your guardians').
- The last section is a special section for a child or young person to read.

However, all sections are written as though the child or young person taking the medicine is reading them.

The sections are:

1. What Exattent XL is and what it is used for
2. What you need to know before you take Exattent XL
3. How to take Exattent XL
4. Possible side effects
5. How to store Exattent XL
6. Contents of the pack and other information
7. Information for children and young people

Now read the rest of this leaflet before you start taking this medicine.

1. What Exattent XL is and what it is used for

What it is used for
Exattent XL is used to treat 'Attention Deficit Hyperactivity Disorder' (ADHD).
- It is used in children and adolescents between the ages of 6 and 18.
- It is used only after treatments which do not involve medicine, such as counselling and behavioural therapy.

Exattent XL 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
Exattent XL 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.

Methylphenidate treatment must only be started by, and used under the regular check-ups of, a specialist in childhood and/or adolescent behavioural disorders. ADHD can be managed using treatment programmes.

About ADHD
Children and adolescents with ADHD find it hard:
- hard to sit still
- hard to concentrate

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

Many children and adolescents struggle to do these things. However, ADHD 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 intelligence of a child or young person.

2. What you need to know before you take Exattent XL

Do not take Exattent XL:
- if you are allergic (hypersensitive) to methylphenidate or any of the other ingredients of this medicine (listed in section 6)
- if you have a thyroid problem
- if you have increased pressure in your eye (glaucoma)
- if you have a tumour of your adrenal gland (phaeochromocytoma)
- if you have an eating problem when you do not feel hungry or want to eat - such as 'anorexia nervosa'
- if you have very high blood pressure or narrowing of the blood vessels, which can cause pain in the arms and legs
- if you 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
- if you 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)
- **if you are currently taking or has taken within the last 14 days an antidepressant (known as a monoamine oxidase inhibitor) – see Taking other medicines**
- if you 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. If you are not sure, talk to your doctor or pharmacist before you take methylphenidate. This is because methylphenidate can make these problems worse.

Warnings and precautions
Tell your doctor or pharmacist before taking this medicine:
- if you have liver or kidney problems
- if you have had fits (seizures, convulsions, epilepsy) or any abnormal brain scans (EEGs)
- if you have ever abused or been dependent on alcohol, prescription medicines or street drugs
- if you are a girl and have started your periods (see the 'Pregnancy, breast-feeding and contraception' section below)
- if you have hard-to-control, repeated twitching of any parts of the body or you repeat sounds and words
- if you have high blood pressure
- if you have a heart problem which is not in the 'Do not take Exattent XL' section above
- if you have a mental health problem which is not in the 'Do not take Exattent XL' 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 before starting treatment. This is because methylphenidate can make these problems worse. If you or your child develop blurred vision or other visual disturbances contact your doctor. Your doctor may consider discontinuation of take Exattent XL.

Checks that your doctor will make before you start taking methylphenidate
These checks are to decide if methylphenidate is the correct medicine for you. Your doctor will talk to you about:
- any other medicines you 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 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 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. Your doctor may decide that other medical tests are needed before you start taking this medicine.

Other medicines and Exattent XL
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take methylphenidate if you:
- 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 are taking other medicines, methylphenidate may affect how well they work or may cause side effects.

If you 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 are taking are included in the list above, ask your doctor or pharmacist before taking methylphenidate.

Having an operation
Tell your doctor if you 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
This medicine may give a positive result when testing for drug use. This includes testing used in sport.

Methylphenidate with alcohol
Do not drink alcohol whilst 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
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 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.

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

Driving and using machines
You may feel dizzy, have problems focusing 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. The medicine can affect your ability to drive as it may make you sleepy or dizzy.
- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
  - o The medicine has been prescribed to treat a medical or dental problem and
  - o You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - o It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

3. How to take Exattent XL

How much to take
Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
- Exattent XL is a "modified release" form of methylphenidate which releases the medicine gradually over a time period corresponding to the school day (8 hours). It is intended to take the place of the same total daily dose of traditional (immediate release) methylphenidate taken at breakfast and lunchtime.
- If you are already taking traditional (immediate release) methylphenidate, your doctor may prescribe an equivalent dose of Exattent XL instead.
- If you have not taken methylphenidate before, your doctor will normally start treatment with traditional (immediate release) methylphenidate tablets. If your doctor feels it is necessary methylphenidate treatment may be started with Exattent XL 10 mg once daily before breakfast.
- Your doctor will usually start treatment with a low dose and increase it gradually as required.
- The maximum daily dose is 60 mg.

How to take
- Exattent XL should be given in the morning before breakfast. The capsules may be swallowed whole with a drink of water, or alternatively, may be opened and the capsule contents sprinkled onto a small amount (tablespoon) of apple sauce and taken immediately and not stored for future use. If the medicine is taken with soft food, some fluids, e.g., water, should be taken afterwards

If you do not feel better after 1 month of treatment
If you do not feel better, tell your doctor. They may decide you need a different treatment.

Not using Exattent XL properly
If Exattent XL 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 Exattent XL than you should
If you 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 or psychosis), 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 forget to take Exattent XL
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 Exattent XL
If you 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 Exattent XL. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Things your doctor will do when you are on treatment
Your doctor will do some tests
- before you start - to make sure that Exattent XL 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 Exattent XL

Long-term treatment
Exattent XL does not need to be taken forever. If you take Exattent XL 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.
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 have any of the side effects below, see a doctor straight away:

Common (affects less than 1 in 10 people)
- uneven heartbeat (palpitations)
- mood changes or mood swings or changes in personality

Uncommon (affects less than 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 (affect less than 1 in 1,000 people)
- feeling unusually excited, over-active and uninhibited (mania)

Very rare (affects less than 1 in 10,000 people)
- heart attack
- fits (seizures, convulsions epilepsy)
- skin peeling or purplish red patches
- 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
- paralysis or problems with movement and vision, difficulties in speech (these can be signs of problems with the blood vessels in your 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

Other side effects (how often they happen is not known)
- unwanted thoughts that keep coming back
- unexplained fainting, chest pain, shortness of breath (these can be signs of heart problems)

If you have 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 (affects more than 1 in 10 people)
- headache
- feeling nervous
- not being able to sleep

Common (affects less than 1 in 10 people)
- joint pain
- dry mouth
- high temperature (fever)
- unusual hair loss or thinning
- feeling unusually sleepy or drowsy
- loss of appetite or decreased appetite
- itching, rash or raised red itchy rashes (hives)
- cough, sore throat or nose and throat irritation
- high blood pressure, fast heart beat (tachycardia)
- feeling dizzy, movements which you cannot control, being unusually active
- feeling aggressive, agitated, anxious, depressed, irritable and abnormal behaviour
- excessive grinding of the teeth (bruxism)

Uncommon (affects less than 1 in 100 people)
- constipation
- chest discomfort
- blood in the urine
- shaking and trembling
- double vision or blurred vision
- muscle pain, muscle twitching
- shortness of breath or chest pain
- increases in liver test results (seen in a blood test)
- anger, feeling restless or tearful, excessive awareness of surroundings, problems sleeping
- dry eye

Rare (affects less than 1 in 1,000 people)
- changes in sex drive
- feeling disorientated
- dilated pupils, trouble seeing
- swelling of the breasts in men
- excessive sweating, redness of the skin, red raised skin rash
- 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))

Very rare (affects less than 1 in 10,000 people)
- heart attack
- sudden death
- muscle cramps
- small red marks on the skin
- inflammation or blocked arteries in the brain
- abnormal liver function including liver failure and coma
- changes in test results - including liver and blood tests
- suicidal attempt, completed suicide, abnormal thinking, lack of feeling or emotion
- fingers and toes feeling numb, tingling and changing colour from white to blue, then red when cold ('Raynaud's phenomenon')

Other side effects (how often they happen is not known)
- migraine
- excessive talkativeness
- very high fever
- slow, fast or extra heart beats
- a major fit ('grand mal convulsions')
- believing things that are not true, confusion
- severe stomach pain, often with feeling and being sick
- prolonged erections, sometimes painful, or an increased number of erections, inability to develop or maintain an erection
- problems with the blood vessels of the brain (stroke, cerebral arteritis or cerebral occlusion)
- inability to control the excretion of urine (incontinence)
- spasm of the jaw muscles that makes it difficult to open the mouth (trismus)
- stuttering
- increased pressure in the eye
- eye diseases which may cause decreased vision due to damage to the eye nerve (glaucoma)

Effects on growth
When used for more than one 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 growth
- Your doctor will carefully monitor height and weight, as well as how well your are eating.
- If you are not growing as expected, then 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 Yellow Card Scheme at 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 Exattent XL

Make sure you keep your medicine in a safe place, so that no one else takes it, especially younger brothers or sisters.

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 blister, bottle and the carton after EXP. The expiry date refers to the last day of that month.

Do not store above 30°C. Keep the bottle tightly closed in order to protect from 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 Exattent XL contains
The active substance is methylphenidate hydrochloride. Each capsule contains 10mg, 20mg, 30mg, 40mg, 50mg or 60mg of methylphenidate hydrochloride.

The other ingredients are:
Capsule content: microcrystalline cellulose spheres, hypromellose, ethylcellulose, hydroxypropylcellulose, dibutyl sebacate, povidone, talc, water.
Capsule shell: hypromellose, titanium dioxide, iron oxide yellow (E172) (20mg, 30mg, 40mg, 50mg), iron oxide red (E172) (40mg, 50mg, 60mg)
Printing ink: shellac, black iron oxide, propylene glycol, ammonia solution, potassium hydroxide

What Exattent XL looks like and contents of the pack
Exattent XL 10 mg modified-release capsules are opaque oblong hard capsules with white cap and white body imprinted with "10" in black ink on body filled with white to off-white spherical pellets. Capsule length: 15.90 ± 0.30 mm.

Exattent XL 20 mg modified-release capsules are opaque oblong hard capsules with ivory cap and white body imprinted with "20" in black ink on body filled with white to off-white spherical pellets. Capsule length: 15.90 ± 0.30 mm.

Exattent XL 30 mg modified-release capsules are opaque oblong hard capsules with yellow cap and white body imprinted with "30" in black ink on body filled with white to off-white spherical pellets. Capsule length: 18.00 ± 0.30 mm.

Exattent XL 40 mg modified-release capsules are opaque oblong hard capsules with orange cap and white body imprinted with "40" in black ink on body filled with white to off-white spherical pellets. Capsule length: 19.40 ± 0.30 mm.

Exattent XL 50 mg modified-release capsules are opaque oblong hard capsules with orange cap and white body imprinted with "50" in black ink on body filled with white to off-white spherical pellets. Capsule length: 21.70 ± 0.30 mm.

Exattent XL 60 mg modified-release capsules are opaque oblong hard capsules with red cap and white body imprinted with "60" in black ink on body filled with white to off-white spherical pellets. Capsule length: 21.70 ± 0.30 mm.

The medicinal product is available in bottles packs containing 28, 30, 50, 60 or 100 capsules.

Not all packs sizes may be marketed.

Marketing Authorisation Holder
STADA, Linthwaite, Huddersfield, HD7 5QH, UK

Manufacturer
Develco Pharma GmbH, Grienmatt 27, DE-79650 Schopfheim, Germany

Other formats
To request a copy of this leaflet in braille, large print or audio please call 01484 842217.

This leaflet was last revised in September 2025

7. Information for children and young people

This info is to help you learn the main things about your medicine called Exattent XL.

If you don't enjoy reading, someone like your mum, dad or carer (sometimes called 'your guardian') can read it to you and answer any questions.

It may help if you read small bits at a time.

Why have I been given this medicine?
This medicine can help children and young people with 'ADHD'.
- ADHD can make you:
  - run about too much
  - not be able to pay attention
  - act quickly without thinking about what will happen next (impulsive).
- It affects learning, making friends and how you think about yourself. It is not your fault.

While you are taking this medicine
- As well as taking this medicine you will also get help with ways to cope with your ADHD such as talking to ADHD specialists.
- This medicine should help you.
- You will need to go to your doctor several times a year for check ups. This is to make sure the medicine is working and that you are growing and developing OK.
- If you take the medicine for more than one year, your doctor may stop your medicine to see if it is still needed. This will probably happen in a school holiday.
- Do not drink alcohol. Alcohol may make the side effects of this medicine worse.
- Girls must tell their doctor straight away if they think they may be pregnant. We do not know how this medicine affects unborn babies. If you are having sex, please talk to your doctor about contraception.

Some people cannot have this medicine
You cannot have this medicine if:
- you have a problem with your heart
- you feel very unhappy, depressed or have a mental illness.

Some people need to talk to their doctor before they start having this medicine
You need to talk to your doctor if:
- you have epilepsy (fits)
- you are pregnant or breastfeeding
- you are taking other medicines – your doctor needs to know about all the medicines you are taking

How do I take my medicine (capsules)?
- Swallow your medicine with water and food.
- Your doctor will tell you how many times a day you should take your medicine
- Do not stop taking the medicine without talking to your doctor first.

Possible side effects
Side effects are the unwanted things that can happen when you take a medicine. If any of the following happen, tell an adult you trust straight away. They can then talk to your doctor.
The main things that could affect you are:
- Feeling worried or nervous
- Feeling dizzy, or getting headaches
- Being very depressed and unhappy or wanting to hurt yourself
- Having different moods than usual, not being able to get to sleep
- Skin rashes, bruising easily, getting out of breath
- The medicine can also make you feel sleepy. If you feel sleepy, it is important not to do outdoor sports like riding a horse or bike, swimming or climbing trees. You could hurt yourself and others.
- Your heart beating faster than usual.

If you feel unwell in any way while you are taking your medicine please tell an adult you trust straight away.

Other things to remember:
- Make sure you keep your medicine in a safe place, so that no one else takes it, especially younger brothers or sisters.
- The medicine is special for you - do not let anyone else have it. It may help you, but it could hurt someone else.
- If you forget to take your medicine don't take two tablets the next time. Just take one tablet at the next normal time.
- If you do take too much medicine, tell your mum, dad or carer right away.
- It is important not to take too much medicine or you will get ill.
- Don't stop taking your medicine until your doctor says it's OK.

Who should I ask if there is anything I don't understand?
Your mum, dad, carer, doctor, nurse or pharmacist will be able to help you.

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