+ SCHWERT
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FALTUNG 3 72.6 MM
FALTUNG 2 107.9 MM
FALTUNG 1 199 MM
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VERSCHLUß-ETIKETT
1053033
Focusim XL
Modified-Release Hard Capsules
Focusim XL
Modified-Release Hard Capsules
1053033
VERSCHLUß-ETIKETT

Package leaflet: Information for the user

Focusim XL 10 mg, 20mg, 30mg & 40mg modified-release hard capsules

Methylphenidate hydrochloride

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 Focusim XL is and what it is used for
2. What you need to know before you take Focusim XL
3. How to take Focusim XL
4. Possible side effects
5. How to store Focusim XL
6. Contents of the pack and other information

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

Focusim XL contains the active substance 'methylphenidate hydrochloride'. It belongs to a group of medicines known as psychostimulants.

What it is used for

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

Focusim XL is not for use as a treatment for ADHD in children under 6 years of age or in patients older than 60 years. It is not known if it is safe or of benefit in these children under 6 years of age.

How it works

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

The medicine is given as part of a treatment programme, which usually includes:
- psychological
- educational and
- social therapy

Focusim XL must only be initiated by, and used under the supervision of a doctor, specialised in the treatment of ADHD, such as an expert paediatrician, a child and adolescent psychiatrist or a psychiatrist. A careful examination by this doctor is required. If you are an adult and have not been treated before, the specialist will carry out tests to confirm that you have had ADHD since childhood. Using treatment programmes as well as medicine helps to manage ADHD.
Contact your doctor if you or your child do not feel any improvement or if you or your child feel worse.

About ADHD

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

Adults with ADHD often find it hard to concentrate. They often feel restless, impatient and inattentive. They may have difficulty organising their private life and work.

Not all patients with ADHD need to be treated with medicine. For children, the decision to use a medicine must be based on a very thorough assessment of the severity and chronic nature of the child's symptoms.

ADHD does not affect intelligence.

Examinations during treatment **Focusim** with XL

Your doctor will regularly check your (or your child's) health while being treated with Focusim XL (please read carefully section 3, 'Things your doctor will do when you or your child are on treatment').

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

Do not take Focusim XL if you or your child:
- are allergic (hypersensitive) to methylphenidate or any of the other ingredients of this medicine (listed in section 6). If you think you are allergic, ask your doctor for advice
- have a thyroid problem
- take a medicine called 'monoamine oxidase inhibitor' (MAOI) used for depression, or if you took an MAOI in the past 14 days (see 'Other medicines and Focusim XL')
- have increased pressure in your eye (glaucoma)
- have a tumour of your adrenal gland (phaeochromocytoma)
- have an eating problem where 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 an inherent 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)
- you have mental health problems such as:
- a 'psychopathic' or 'borderline personality' problem
- abnormal thoughts or hallucinations, 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
- mood changes from depression to mania

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Focusim XL if you or your child:
- have liver or kidney problems
- develop blurred vision or other visual disturbances contact your doctor. Your doctor may consider discontinuation of Focusim XL.
- have had fits (seizures, convulsions, epilepsy) or any abnormal brain scans (EEG)
- have ever abused or been dependent on alcohol, prescription medicines or street drugs
- are female and have started having periods (see section 'Pregnancy, breast-feeding and fertility' below)
- or any other member of your family 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 Focusim XL"
- have a mental health problem which is not mentioned in the section "Do not take Focusim XL". Other mental health problems include:
- mood swings (from being manic to being depressed - called 'bipolar disorder')
- starting to be aggressive or hostile, or aggression which 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 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.

During treatment, boys and men 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, 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.

If you or your child have or have had heart problems before starting treatment or develop heart symptoms during treatment with Focusim XL, tell your doctor immediately, who will refer you to a heart specialist.

Drug testing/anti-doping testing

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

Other medicines and Focusim XL

Tell your doctor or pharmacist 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 blood pressure (see "Do not take Focusim XL")

If you or your child are taking other medicines, methylphenidate may affect how well they work or may cause side effects. It may therefore be necessary to change the dose of the medicine or to discontinue treatment alltogether. 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 (e.g. schizophrenia)
- medicines for epilepsy
- medicines used to reduce or increase blood pressure
- some cough and cold remedies which contain substances that can affect blood pressure. It is important to check with your pharmacist when you buy any of these medicines
- 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 for advice before taking methylphenidate.

Having an operation

Tell your doctor that you or your child are being treated with Focusim XL if you or your child is going to have an operation. Methylphenidate should not be taken on the day of 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.

Focusim XL with food, drink and alcohol

Focusim XL may be taken with or without food. Taking methylphenidate with food may help to stop stomach pain, nausea and being sick. If you or your child notice a decrease in appetite while taking this medication, try to avoid taking it just before a meal. Instead, try taking it with food or after finishing eating.

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 or pharmacist for advice before taking this medicine.

Available data does 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.

Ask your doctor or pharmacist for advise before taking this medicine if you or your daughter are:
- sexually active. Your doctor will discuss contraception
- pregnant, may be pregnant or are planning to become pregnant. Your doctor will decide whether you should take methylphenidate
- are breast-feeding or are planning to breast-feed. It is possible that methylphenidate is passed into breast milk. Therefore, your doctor will decide whether you should breast-feed while taking methylphenidate

No effects on fertility have been seen in animal tests.

Driving and using machines

You or your child may feel dizzy or sleepy, have problems focussing or have blurred vision, have hallucinations or other side effects of the central nervous system 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.

Focusim XL contains sucrose (sugar spheres)

If you have been told by your doctor that you or your child have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Focusim XL

You or your child should always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
The capsules contain two different types of beads. Half of the beads release the active substance (methylphenidate) directly after intake and the other half of the beads release methylphenidate after 4 hours.

Dose

Your doctor will usually start treatment with a low dose and increase it gradually as required. Focusim XL should not be taken too late in the day, in order to prevent sleep disturbances.

Children (6 years and over) and adolescents

The recommended starting dose is 20 mg once daily. At the discretion of the doctor, treatment with Focusim XL can also be started at a dose of 10 mg. The maximum daily dose is 60 mg. Focusim XL is taken once daily in the morning in patients younger than 18 years of age.

Adults

The maximum daily dose is 80 mg.
- If you take Focusim XL for the first time, your doctor will start treatment at a dose of 20 mg once daily and, if required, will increase the dose gradually at weekly small increments. Treatment with Focusim XL can also be started with an initial dose of 10 mg daily at the doctor's discretion.
- If you were already treated with a modified-release formulation or any other methylphenidate preparation with a similar release system in childhood and you have just turned 18, your doctor may continue treatment with the same dose. If you were treated with an immediate-release formulation in childhood, your doctor will prescribe the equivalent dose of Focusim XL
- In adults, Focusim XL is taken once daily, usually in the morning.

For lower doses or smaller increments, different strengths of this medicine and other methylphenidate-containing medicines may be available.

Things your doctor will do when you or your child is on treatment

Your doctor will do some tests:
- before you or your child starts –to make sure that Focusim XL is safe and will be of benefit (listed in section "Checks that your doctor will make before you or your child start taking methylphenidate")
- after you or your child starts – 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 appetite
- measuring height and weight for children and adolescents
- measuring weight for adults,
- measuring blood pressure and heart rate
- checking for problems with mood, state of mind or any other unusual feelings, or if these have become worse while taking Focusim XL

Method of Administration

Focusim XL is for oral use.
- take Focusim XL once daily with or without food. Focusim XL should not be taken too late in the morning as it may cause disturbances in sleep
- the capsule should be swallowed whole, with a drink of water
- do not crush, chew or divide the capsule or the contents

If you or your child are unable to swallow Focusim XL you can sprinkle the contents on a small amount of food, as follows:
- carefully open the capsule and sprinkle the pellets over a small amount of soft food (e.g. apple sauce, jam, spread, yoghurt).
- the food should not be warm because this could affect the special properties of the pellets.
- do not crush or chew the pellets.
- immediately eat all of the drug/food mixture.

Do not store any drug/food mixture for future use.

Long-term treatment

Focusim XL should not and does not need to be taken forever. If you or your child takes Focusim XL for more than one year, your doctor should stop treatment for a short time at least once a year (in children, this may happen during a school holiday). This will show if the medicine is still needed.

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. He may decide that you or your child need a different treatment.

Not using Focusim XL properly

If Focusim XL is not used properly, this may cause abnormal behaviour. It may also mean that you or your child starts to depend on the medicine. Attention should be paid to the risk of diversion, misuse, and abuse of this medicine.

Long-term abuse of Focusim XL may lead to a lack of efficacy of usual doses (tolerance), psychological dependence, abnormal behaviour, or psychotic episodes (hallucinations, delusions). It may also mean that you or your child become dependent 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 Focusim XL than you should

If you or your child have taken too many capsules, talk to a doctor or call an ambulance straight away. Tell them how much has been taken. Medical treatment might be needed.

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 spasm, fever, red-brown urine which could be possible signs of abnormal breakdown of muscles (rhabdomyolysis).

If you or your child forget to take Focusim XL

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

If you or your child stop taking Focusim XL

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

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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 experience any of the side effects below, see a doctor straight away:

Common (may affect up to 1 in 10 people)
- Uneven/ irregular heartbeat (palpitations, arrhythmia)
- mood changes, mood swings or changes in personality

Uncommon (may affect up to 1 in 100 people)
- thinking about or feeling like killing yourself
- mood changes or mood swings
- seeing, feeling, or hearing things that are not real (hallucinations), these are signs of psychosis
- uncontrolled speech and body movements (tics, Tourette's)
- heart murmur (detected by auscultation of the heart)
- 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
- blood in the urine

Rare (may affect up to 1 in 1,000 people)
- feeling unusually excited, over-active and uninhibited (mania)

Very rare (may affect up to 1 in 10,000 people)
- unexplained fainting, chest pain, shortness of breath - these can be signs of heart problems (inc. heart attack)
- fits (seizures, convulsions epilepsy)
- skin peeling (exfoliative dermatitis) or purplish red patches (purpura)
- suicidal attempt (including completed suicide)
- 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
- inflammation or blocked arteries in the brain
- 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
- yellowing eyes/skin (jaundice), abdominal pain and swelling in the legs and ankles – these may be the signs of liver failure and can lead to coma

Not known (frequency cannot be estimated from the available data)
- unwanted thoughts that keep coming back
- prolonged erections, sometimes painful, or an increased number of erections
- unexplained fainting, chest pain, shortness of breath (these can be signs of heart problems)
- problems with blood vessels in the brain (stroke, cerebral arteritis, or cerebral occlusion)
- a major fit ('grand mal convulsions')
- dependence on methylphenidate

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

Common (may affect up to 1 in 10 people)
- joint pain
- high temperature (fever)
- unusual hair loss or thinning
- feeling unusually sleepy or drowsy
- loss of appetite
- weight decrease in adults
- reduced weight gain and growth retardation during prolonged use in children
- panic attack
- decrease in sex drive
- toothache
- excessive teeth grinding (bruxism)
- itching, rash or raised red itchy rashes (hives)
- excessive sweating
- cough, sore throat or nose and throat irritation, shortness of breath or chest pain
- changes in blood pressure (mainly high blood pressure, fast heart beat (tachycardia), cold hands and feet
- shaking or trembling, feeling dizzy, movements which you cannot control, feeling jittery, being unusually active
- feeling aggressive, agitated, restless, anxious, depressed, stressed, irritable and abnormal behaviour, problems sleeping, tiredness
- stomach pain, diarrhoea, stomach discomfort, indigestion, thirst and being sick.

These side effects usually occur at the start of treatment and can be reduced by taking the medicine with food.

Uncommon (may affect up to 1 in 100 people)
- constipation
- chest discomfort
- blood in the urine
- double vision or blurred vision
- muscle pain, muscle twitching, muscle tightness
- increases in liver test results (seen in a blood test)
- anger, feeling tearful, excessive awareness of surroundings, tension
- stomach pain, often with nausea, vomiting, and diarrhoea (gastroenteritis)
- a compelling need to move (akathisia)
- dry eye

Rare (may affect up to 1 in 1,000 people)
- changes in sex drive
- feeling disorientated
- dilated pupils, trouble seeing
- swelling of the breasts in men
- 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 (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
- very high fever
- chest discomfort
- slow, fast or extra heart beats
- a major fit ('grand mal convulsions')
- believing things that are not true (delusions), confusion
- excessive uncontrolled talking
- severe stomach pain, often with feeling and being sick
- erectile dysfunction
- prolonged erections, sometimes painful, or an increased number of erections
- inability to control the excretion of urine (incontinence)
- spasm of the jaw muscles that makes it difficult to open the mouth (trismus)
- stuttering
- nosebleed
- increased pressure in the eye
- eye diseases which may cause decreased vision due to damage to the eye nerve (glaucoma)

Effects on growth in children

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 height increase
- your doctor will carefully monitor height and weight, as well as how well your child is eating
- if your child is 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 the 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 Focusim XL

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

Make sure to store the medicine in a secure place so that nobody else can take it.

Do not use this medicine after the expiry date, which is stated on the carton box and bottle after {EXP}. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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

6. Contents of the pack and other information

What Focusim XL contains

The active substance is methylphenidate hydrochloride.

Focusim XL 10 mg modified-release hard capsules
Each hard capsules contain 8.65 mg methylphenidate as 10 mg methylphenidate hydrochloride.

Focusim XL 20 mg modified-release hard capsules
Each hard capsules contain 17.3 mg methylphenidate as 20 mg methylphenidate hydrochloride.

Focusim XL 30 mg modified-release hard capsules
Each hard capsules contain 25.95 mg methylphenidate as 30 mg methylphenidate hydrochloride.

Focusim XL 40 mg modified-release hard capsules
Each hard capsules contain 34.6 mg methylphenidate as 40 mg methylphenidate hydrochloride.

The other excipients are:

Capsule contents:
Cellulose, microcrystalline, hypromellose, talc, methacrylic acid-methyl methacrylate copolymer (1:1), triethyl citrate, ethylcellulose, hydroxypropylcellulose

Capsule shell:
Focusim XL 10 mg, 30mg & 40mg modified-release hard capsules
Gelatin, titanium dioxide (E171), iron oxide yellow (E172)
Focusim XL 20 mg modified-release hard capsules
Gelatin, titanium dioxide (E171)

Printed ink:
Shellac glaze, Iron oxide black (E172), Propylene glycol

What Focusim XL looks like and contents of the pack

Modified-release hard capsules

Focusim XL 10 mg modified-release hard capsules
Opaque hard gelatine capsule (size 3) with rich yellow cap and white body imprinted "10" with black ink, filled with white to off-white spherical pellets. Capsule length: 15.9 mm.

Focusim XL 20 mg modified-release hard capsules
Opaque hard gelatine capsule (size 3) with white cap and white body, imprinted "20" with black ink, filled with white to off-white spherical pellets. Capsule length: 15.9 mm.

Focusim XL 30 mg modified-release hard capsules
Opaque hard gelatine capsule (size 2) with ivory cap and ivory body, imprinted "30" with black ink, filled with white to off-white spherical pellets. Capsule length: 18 mm.

Focusim XL 40 mg modified-release hard capsules
Opaque hard gelatine capsule (size 1) with rich yellow cap and rich yellow body, imprinted "40" with black ink, filled with white to off-white spherical pellets. Capsule length: 19.4 mm.

Focusim XL modified-release hard capsules are available in:

HDPE bottles with child-resistant closure (PP)
Or
Child-resistant aluminium/PVC/PE/PVDC blisters
10, 28, 30, 40, 50, 56, 60, 84, 100 modified-release hard capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Strides Pharma UK Limited
Unit 4, The Metro Centre Dwight Road,
Watford WDl8 9SS,
United Kingdom

Manufacturer

A&O Pharma GmbH, Am Sattel 17, D-79588, Efringen-Kirchen, Germany

This leaflet was last revised in 05/2026.

Information for children and young people

This info is to help you learn the main things about your medicine called Focusim 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 and doing homework, 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. But it does not cure ADHD.
- 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.
- you suffer from an eating disorder.

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
- If necessary, you can open the capsule and sprinkle the beads over a small amount of soft food (e.g., apple sauce, jam, spread, yoghurt). The food should not be warm because this could affect the medicine. Immediately swallow all of the medicine/food mixture.
- the capsules and/or their contents must not be crushed or chewed.
- 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:
- You cannot sleep or you sleep badly
- You feel or are sick, have tummy pains, or diarrhoea. It is best to take the medicine with foord
- Feeling worried or nervous
- Feeling dizzy, or getting headaches
- Being very depressed and unhappy or wanting to hurt yourself or are unusually anxious
- Having different moods than usual or are unusually active, or unusually aggressive, not being able to get to sleep
- Skin rashes, itchy skin, bruising easily, getting out of breath
- You lose more hair than usual
- 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 or irregularly.
- You have poor appetite, do not grow as fast as your friends or classmates of the same age.
- You have to cough, your throat hurts, or you have trouble swallowing
- You feel run down and have difficulty moving
- You have a fever

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 capsules the next time. Just take one capsule 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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