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FALZWERK 23 X WICKELFALZ

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VERSCHLUP-ETIKETT

VERSCHLUP-ETIKETT

Package leaflet: Information for the user

Focussin XL 10 mg, 20 mg, 30 mg & 40 mg 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

- What Focussin XL is and what it is used for
- What you need to know before you take Focussin XL
- How to take Focussin XL
- Possible side effects
- How to store Focussin XL
- Contents of the pack and other information

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

What it is used for

Focussin 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

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

How it works

Focussin 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

Focussin 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.

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.

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

Do not take Focussin XL if you or your child:

- are allergic 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
- have increased pressure in your eye (glaucoma)
- have a tumour of your adrenal gland (pheochromocytoma)
- 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 inherited 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 excited, over-active, and over-enthusiast
 - 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 Focussin 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 Focussin 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 Focussin XL"
- have a mental health problem which is not mentioned in the section "Do not take Focussin 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 it 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 unexpected 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.

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 Focussin 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 Focussin 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 altogether. 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 Focussin 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.

Focussin XL with food, drink and alcohol

Taking methylphenidate with food may help to stop stomach pain, nausea and being sick.

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

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 advice 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 drowsy 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.

3. How to take Focussin 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.

Dose

Your doctor will usually start treatment with a low dose and increase it gradually as required.

Children (6 years and over) and adolescents

The recommended starting dose is 20 mg once daily. At the discretion of the doctor, treatment with Focussin XL can also be started at the dose of 10 mg. The maximum daily dose is 60 mg. Focussin 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 Focussin 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.
- 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 Focussin XL.

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 Focussin 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,
- 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 Focussin XL.

Method of Administration

Focussin XL is for oral use.

- take Focussin XL once daily with or without food. Focussin 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 Focussin 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).
- 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

Focussin XL should not and does not need to be taken forever. If you or your child takes Focussin 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 Focussin XL properly

If Focussin 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. 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 Focussin 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.

If you or your child forget to take Focussin 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 Focussin 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 Focussin XL.

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

Common (may affect up to 1 in 10 people)

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Front Side

NON PRINTING COLOUR

CMO - ARTWORK DETAIL LABEL

PRODUCT		Focussin XL Modified-Release Hard Capsules 10,20,30,40 mg		MFG. LOCATION		Kanapharma AG	
BUYER/COUNTRY		SPUK		COMPONENT		Outer	
DIMENSION		625 x 397 mm		PACK		---	
NEW ITEM CODE		1052635		OLD ITEM CODE		1051290	
COLOUR SHADES		BLACK		No. of Colours		1	
Change Control No.		FC-SPU/2025/021 - Revised Number: 468793		Artwork Version		2.0	
Design/Style		Front & Back Side printing.					
Substrate		As per CMO Specification					
Special Instructions		PRINTING CLARITY TO BE CLEAR AND SHARP.					
Autocollator Requirements		NA					

Caution to the printer: before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONT/DESIGN error mismatching with the APPROVED ARTWORK, please inform SCM / PD / FO further ASAP. Do NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM SCM / PD.

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