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Package leaflet: Information for the user

Focusim XL 10 mg, 20 mg, 30 mg & 40 mg modified-release hard capsules $$\operatorname{Methylphenidate}$ hydrochloride

and 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, and your decier or pharmacist. This medicine has been prescribed for you will, 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 Focusim XL is and what it is used for
 What you need to know before you take Focusim XL
 How to take Focusim XL
 Possible side effects
 How to store Focusim XL
 Contents of the pack and other information

- What Focusim XL is and what it is used for

What it is used for

Focusion XI. It is used to treat 'Attention Deficit Hyperactivity Disorder' (ADHD).

— it is used in children and adolescence 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.

useim 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 se children under 6 years of age.

those children under by years of age.

How it works
Focusin XI. Improves the activity of certain parts of the brain which are under-active. The medicine can help improve attenspans and concentration, and rothce impulsive behaviour.

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

— psychological

— obscalational and

— social thinoups

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 pacelatrician, 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 programmers as well as medicine helps to manage ADHD.

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

not their fault that they cannot do these things

Among which mad addressen straigle to the the 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.

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

sugasising titer private lite 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.

- therough ascourant of the severity and chrone nature of the child's symptoms.

 ADITO does not after Teachist irrellingence.

 2. What you need to know before you take Focusion XI.

 Do not take Focusion XI. If you or your Child is not continued to the impredients of this medicine (listed in section 6). If you take you are allerge to methylphenisting or any of the other ingredients of this medicine (listed in section 6). If you take he was ally one of the continued to the continued of the properties of the propert

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 do

- XL. have had fix (seizures, convolutions, epilepsy) or any abnormal brain scans (EEG) have ever abneed or been dependent on alcohol, prescription medicines or attent drugs, the product of the production of the

Lave a mental health problem which is not mentioned in the section "Do not take Focusins XL". Other mental heatin problems include:

mond swings (from being matric to being depressed - called 'biploaf dinorder') stating to be agreated; we have the part of the problems o

- rear you ancesse wa paramament, if any of the elsows applies to byour of your circums, control entering treatment. That is because the control phenomena can make these problems were. Your decive will want to monitor how the moderical affects you or your child. During treatment, byou and men may unexpectedly experience prolonged exercisors. This may be painful and can occur at any time. It is important to contact your deciver reducing lower you or your child start taking methylphenidate.

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

 These etches are to docide introhylphenidate is the corner neclined on Foy or your child. Your doctors will talk to you about:

 **whether there is any family history of stadion unexplained death

 any other medical problems (used as hear problems) you, your child or your family may have

 how you or your child are feeling, such as feeling higher of you, having strange floughts, or if you or your child have had any

 of these feelings in the past

 **whether there is a family history of 'tice', (hand-to-control, repeated twicking of any pasts of the body are regarding sounds

 and world).

 **whether there is a family history of 'tice', thand-to-control, repeated twicking of any pasts of the body are regarding sounds

 and world).

 **doctors whether you or your child are at risk of having mood wrings (from being munic to being depressed called 'hipolan'

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 disounds'. Your doctor will check you or your child are at risk of having mood wrings (from being munic to being depressed called 'hipolan'

 disounds'. Your doctor will check you or your child are multin history, and deck of any of your dish has a history of incorder or depression.
- important that you provide as much information as you can. This will help your doctor decide if methylphenidate is the corricinte for you or your child. Your doctor may decide that other medical tests are needed before you or your child. So we have the some decide that other medical tests are needed before you or your child start taking medicine.

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Drug testing/anti-doping testing
This medicine may give a positive result when testing for drug use. This includes testing used in sport.

Other medicine and Fecusion XI.

The gree closes or glob meanine if you or your child are taking, have recently taken or might take any other medicines.

Do not take methylpheniates if you or your child:

— are taking a medicine called a "measurine coulsine inhibitor" (MAOI) used for depression, or have taken an MAOI in the last 14

days. Taking an MAOI with methylpheniates may cause a sudden increase in blood pressure (see "Do not take Focusion XII")

Type or your child are taking other medicines, methylpheniates may dried how well they work or may causes side effects. It may therefore be necessary to change the dose of the medicine or to discontinue treatment allogedire. If you or your child are taking one of the following another, tacks with your dector or planemator before taking methylpheniates:

- for depression were mental health problems (e.g. schizophrenia)
- motivate modelines for depression
 modelines for severe mental health problems (e.g. schi
 modelines for severe mental health problems (e.g. schi
 modelines severe mental health problems (e.g. schi
 modelines severe to reduce or increase blood pressure
 some cough and cold remodles which contain substam
 pharmacist when you boy any of these modelines
 modelines that this the blood to prevent blood clost
 If you are in any doubt about whether any modelines you on
 pharmacist for advice before taking methylphenidate. ices that can affect blood pressure. It is imp
- u or your child are taking are included in the list above, ask your doctor of

or a sudden rase in blood pressure during the operation.

Focusin M.J. with food, drink and alrebal

Taking methylphendure with food may belp to stop stomach pain, nausea and being sick.

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

Pregnancy, breast-feeding and fertility Available data does not suggest an increas sed risk of overall birth defects, whilst a small increase in the risk of malformation months of pregnancy could not be ruled out. Your doctor will be able to give you

and the second s

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

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

librar (6 years and over) and adolescents
recommended starting dose is 20 mg once daily. At the discretion of the doctor, treatment with Focusim XL can also be started
dose of 10 mg. The maximum daily dose is 60 mg. Focusim XL is taken once daily in the morning in patients younger than
years of age.

maximum duly done is 80 mg.

If you take Focusin K.E the first time, your doctor will start treatment at a done of 20 mg once duly and, if required, will increase the done gradually at weekly small increments.

If you were already better down has mediate-decises formulation or any other methylphenidate preparation with a similar release system in childhood and you have just harmed 18, your doctor may continue treatment with the same done. If you were tracted with a minimized eveluse formulated release formulation in childhood, your doctor will prescribe the operation does of Fersians XI. For lower doses or smaller increments, different strengths of this medicine and other methylphenidate-containing medicines may

be available.

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

Vour dector will do some texts:

**Define your your child your your your child in the Froution XI. is safe and will be of benefit (listed in section "Checks that the your child starts you your child starts are your period better taking your period with your your your child starts are how will be done at least every 6 months, but possibly more often. They will also be done when the done is changed

- when the does is changed to tests will include the close that will reduce the change apoptite measuring height and weight for children, measuring weight for adults, measuring weight for adults, measuring bood pressure and heart rate checking for problems with mood, state of mind or any other unusual feelings, or if these have become wone while taking Feestiam XI.

- Focusin XI. for oral true.

 and Administration

 sim XI. is for oral true.

 that Focusin XI. does daily with or without food. Focusin XI. should not be taken too late in the moming as it may ex
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- to not triate, there we derive the exposure to the contents of the contents on a small amount of 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 their could affect the special properties of the pellets. intermediately careful for the drug food mixture.
- Do not store any drug/food mixture for future use.

Long-term treatment
Focusion XL should not and does not need to be taken forever. If you or your child takes Focusion 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. Tell your doctor if you or your child has ever abused or been dependent on alcohol, prescription medicines or

If Focusin M. As its on was a present of the control of the medicine. They gour deposit you or your child has ever abused or near support of the control of the medicine is only for you or your child. Do not give this medicine to anyone cloc, even if their symptoms seem similar. This medicine is only for you or your child. Do not give this medicine to anyone cloc, even if their symptoms seem similar.

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 Forenim XI.

If you or your child sudenly due taking this medicine, the ADHD symptoms may come back or unwanted effects such as depression may sport. For declore may want be grabally reduce the amount of medicine taken each day before supping it employed. Take types develor supping Forenia for producing the complexity. Take your doctor or plantments.

4. Possible side effects
Like all modicines, this modicine can cause side effects, although not everybody gets them. Although some people get side effects most people find that methylphemidate 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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CMO - ARTWORK DETAIL LABEL								
		MFG. LOCATION	Konapharma AG					
PRODUCT	Focusim XL Modified-Release Hard Capsules 10,20,30,40 mg							
BUYER/COUNTRY	SPUK	COMPONENT	Outsert					
DIMENSION	625 x 397 mm			PACK				
NEW ITEM CODE	1052635	OLD ITEM CODE	1051290					
COLOUR SHADES	BLACK			No. of Colours	1			
Change Control No.	PC-SPU/2025/021 - Record 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.							
Autocartonator Requirements	NA							
provided to you. In ca	r: Before processing, please ensure that the ARTWO se of any FONTS/DESIGN are Mis-matching with the CHANGE TO THE ARTWORK WITHOUT WRITTEN III	e APPROVED ARTW	ORK, please inform					



- uneven heartheat (palpitations) - uneven heartheat (palpitations) Utcommon (may affect up to 1 in 100 people) Utcommon (may affect up to 1 in 100 people) - technic, feeling, or hearing filling, that are not real - these are signs of psychosis uncontrolled spech and body movements (Tourette's) - signs of allergy such as real, tiching or thive on the skin, welling of the face, lips, tongue or other parts of the body, stortness of Proofs, wheeting or trouble breathing Contents of the pack and other information The acrow austrance is mentyphenicalize hydrocinorion. Focusin XL, 10 mm ondificul-release hard capsules. Each hard capsules contain 8.65 mg methylphenidate as 10 mg methylphenidate hydrochloride. Focusin XL, 20 mm ondificul-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. - blood in the usine Rare (may affect up to 1 in 1,000 people) feeding unusually excited, over-active and uninhibited (mania) Focusim XL 40 mg modified-release hard capsules Each hard capsules contain 34.6 mg methylphenidate as 40 mg methylphenidate hydrochloride. 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 Notember-brease natic cipature. Focusin XI. In prooffied-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 pellots. Capsule length: 153 mm. white spherical pellets. Capusa length: 15.9 mm. Fessions M. 2.0 mm modified release hand gasales Opaque hard gelatine capusal (aire 3) with white cap and white body, imprinted "20" with black ink, filled with white to off-white spherical pellets. Capusal length: 153 met. Focusim XI. 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. common (nor affect up to 1 in 10 people) Common (nor affect up to 1 in 10 people) high temperature (fever) unusual hair loss or thinning feeling unusually skeep or drowy eling the control of the co 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 10, 28, 30, 40, 50, 56, 60, 84, 100 modified-release harn 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, Waffeed WDB 95S. United Kingdom Manufacturer A&O Pharma GmbH, Am Sattel 17, D-79588, Efringen-Kirchen, Germany This leaflet was last revised in 09/2025. 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. Information for children and young people These sade effects usually occur at the start of treatment a Uncommon (nga Affect up to 1 in 100 people) constipation chest discomfort double vision or blurred vision muscle pair, muscle twisching, muscle tightness increases in liver test results (seen in a blood test) anger, feeling tearful, excessive awareness of surror dry eye

- dry ope

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

 changes in sex drive

 felling discrimented

 dilated papit, truoble seeing

 swelling of the treats in men

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 refuses of the skin, red mised kin reals

 Obsessive complete discoder (COCD) (including irresistible targe to pull out body hair, skin picking, having repeated

 uns anated thoughts, feelings, images or targes in your mind (obsessive thoughts), performing repeated behaviours or mental

 ritant (competitions) rituals (compulsions)

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

 mande carmy
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 mande carmy
 in the skin
 charge in test results including liver and blood tests
 charges in test results including or emotion
 fingers and toes feeling numb, tingling and changing colour from white to blue, then red when cold ('Raysaud's
 phenomenon')

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

- It known (frequency cannot be estimated from the available data) mignine very high frequency and the continued of the continu

eye discusses which may cause decreased vision due to damage to the eye nerve (gluscoma) Elects on growth in children Elects 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 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 enting 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, addits a your doctor or pharmaciat. This includes any possible side effects not instal in this leaflet. You Tyou get any side effects, addits a your doctor or pharmaciat. This includes any possible side effects not instal in this leaflet. You Cord in the Coogle Figure Apple Apple Supplement or search for 'MIRA Yellow Day reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Focusin XI.
See How to store Focusin XI.
Keep this medicate out of the sight and reach of children.
Keep this medicate out of the sight and reach of children.
Keep this medicate out of the sight and reach of the store place to that necket place to that the interest place in the store place to the store plac

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.

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

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

As well at a tanger menecutive year with a soo get early with ways to cope with your AUTUI state in an attention to AUTUI. This medicine the should help you. You will need to go to your dector several times a year for check up. This is to make sure the medicine is working and that you are growing and teveloping (OK.
If you take the medicine for more than one year, your dector may stop your medicine to see if it is still needed. This will be not drink alcohol. Alcohol may make the side effects of this medicine wore.
Girls must lett their dector straight away if they think they may be pregnant. We do not know how this medicine affects undernot holds. If you are having see, place that key your decire 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:

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.

Possiles used effects

State effects are the unwanted things that can happen when you take a medicine. If any of the following happen, tell an adult you must straight eavy. They can then talk to your doctor. The main things that could affect you are:

Feeding durzy, or getting headaches

Feeding durzy, or getting headaches

Being very depressed and unhappyre or wanting to hart yourself!

Having different mooth that usual, not being able to get to skeep

Having different mooth that usual, and being dark less get to skeep

The medicine can also makes you feed below. If you feed a sleep, it is important not to do outdoor sports like riding a horse or blac, swimming or climbing trees. You could hart yourself and others.

Vow heart beautiful faster that musal.

It you feet earnest in any way wante; you are taxing; your necessive peaces test an auturity you treas straight away.

Make user you keep your medicine in a safe place, so that no one clee takes is, especially younger brothers or.

The medicine is special for you — 6- no not let anyone clee have it. It may help you, but at could hust someone clee.

If you fought to one him dendries, elfly your man, add or creat right away.

It is important not to take to much medicine don't your man, add or creat right away.

It is important not to take to much medicine of you will get ill.

Don't shop highly your medicine und your declor way si & 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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Substrate	As per CMO Specification.								
Special Instructions	PRINTING CLARITY TO BE CLEAR AND SHARP.								
Autocartonator 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 FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform SCM / PD for further action DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM SCM / PD.									
RDPD/008/F-01/R									