

## Module 1.3.1

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### Package leaflet: Information for the patient

#### Tentin 5 mg tablets

Dexamfetamine sulphate

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

**Read all of this leaflet carefully before your child starts taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same.
- If your child gets 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 Tentin 5 mg is and what it is used for
2. What you need to know before you use Tentin 5 mg
3. How to use Tentin 5 mg
4. Possible side effects
5. How to store Tentin 5 mg
6. Contents of the pack and other information

### 1. WHAT TENTIN IS AND WHAT IT IS USED FOR

#### What Tentin 5 mg is

Tentin 5 mg tablets contain the active substance dexamfetamine sulphate.

Tentin 5 mg is a psychostimulant. It improves activity in parts of the brain. This medicine can help to improve attention span, concentration, and reduce impulsive behaviour.

#### What it is used for

Tentin is used to treat attention-deficit/hyperactivity disorder (ADHD).

- it is used in children and adolescents aged 6-17 years.
- it is not indicated in all children with ADHD
- it is used only after when another medicine called methylphenidate was not sufficiently effective.
- It should be used as part of a treatment programme which typically includes psychological, educational and social measures.

Tentin treatment must only be initiated by, and used under the supervision of a specialist in childhood or adolescent behavioural disorders.

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You must talk to a doctor if your child does not feel better or if they feel worse after a month. The doctor may decide that a different treatment is needed.

### 2. WHAT YOU NEED TO KNOW BEFORE YOU USE TENTIN

#### Do not use Tentin if your child:

- is allergic (hypersensitive) to dexamfetamine or other amphetamine compounds or any of the other ingredients of Tentin (listed in Section 6)
- has a thyroid problem
- has increased pressure in the eyes (glaucoma)
- has a tumour of the adrenal gland (phaeochromocytoma)
- has an eating problem, does not feel hungry or does not want to eat (e.g anorexia nervosa)
- has very high blood pressure or narrowing of the blood vessels, which can cause pain in the arms and legs
- has advanced arteriosclerosis
- has ever had heart problems - such as a heart attack, uneven heartbeat, pain and discomfort in the chest, heart failure, heart disease, or was born with a heart problem
- has had a problem with the blood vessels in the 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)
- has mental health problems such as:
  - a psychopathic or borderline personality disorder
  - abnormal thoughts or visions or schizophrenia
  - signs of a severe mood disorder like:
    - suicidal feelings
    - severe depression
    - mania
- is currently taking or has taken within the last 14 days an antidepressant (known as a monoamine oxidase inhibitor) – see the ‘Other medicines and Tentin’ section below
- has ever abused alcohol, prescription medicines, or street drugs
- or anyone in your family has Tourette’s syndrome or other motor or verbal tics
- has hard-to-control, repeated twitching of any parts of the body or repeats sounds and words
- has porphyria

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

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Tentin if your child

- has a disease of the blood or liver, or kidney problems
- is hyperexcitable or has an unstable personality
- has had fits (seizures, convulsions, epilepsy) or any abnormal brain scans (EEGs)
- is female and has started having periods (see the ‘Pregnancy and breast-feeding’ section below)
- has high blood pressure
- has a heart problem which is not in the ‘Do not take’ section above

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- has a mental health problem which is not in the ‘Do not take’ section above. This may include mood swings, unusual aggression, hallucinations, delusions, paranoia, agitation and anxiety, feelings of guilt or depression.

Tell your doctor or pharmacist if any of the above applies to your child before starting treatment. This is because this medicine can make these problems worse. Your doctor will want to monitor how the medicine affects your child.

### Checks that your doctor will make before Tentin is used

These checks are to decide if this is the correct medicine for your child. Your doctor will talk to you about:

- any other medicines your child is 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 your child is feeling, such as feeling high or low, having strange thoughts or if your child has 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 your child is at risk of having mood swings (from being manic to being depressed - called ‘bipolar disorder’). They will check 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 Tentin is the correct medicine for your child. Your doctor may decide that other medical tests are needed before they start taking this medicine.

### Effect on weight/growing

Tentin may cause reduced weight in some children and adolescents.

- There may be lack of weight gain
- Your doctor will carefully watch the height and weight of your child, as well as how well your child is eating.
- If your child is not growing as expected, then your doctor may stop treatment with Tentin for a short time.

### Having an operation

Tell your doctor if your child is going to have an operation. Tentin 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.

### Drug testing

This medicine may give a positive result when testing for drug use. Athletes must be aware that this medicinal product may cause a positive reaction to ‘anti-doping’ tests.

### Children and adolescents

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

### Other medicines and Tentin

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines, including medicines obtained without a prescription.

#### Monoamine oxidase inhibitors

Do not use this medicine if your child is taking a medicine called a ‘monoamine oxidase inhibitor’ (MAOI) used for depression, or has taken an MAOI in the last 14 days. Taking an MAOI with dexamfetamine may cause a sudden increase in blood pressure.

If your child is taking other medicines, this medicine may affect how well they work or may cause side effects. If your child is taking any of the following medicines, check with your doctor or pharmacist before using Tentin:

- other medicines for depression, e.g. tricyclic antidepressants and selective serotonin reuptake inhibitors
- medicines for severe mental health problems, e.g. phenothiazines and haloperidol
- medicines for epilepsy, e.g. anticonvulsants like phenobarbital, phenytoin, primidone, and ethosuximide
- medicinal products that help to give up alcohol, e. g. disulfiram
- medicines used to reduce or increase blood pressure, e.g. guanethidine, clonidine, reserpine, or alpha-methyltyrosine, or beta-blockers such as propranolol
- 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, e.g. coumarin anticoagulants
- any medicines that contain glutamic acid HCl, ascorbic acid, ammonium chloride, sodium acid phosphate, sodium bicarbonate, acetazolamide, thiazides
- any of the following medicines: beta-blockers, antihistamines, lithium, noradrenaline, morphine, and meperidine

If you are in any doubt about whether any medicines your child is taking are included in the list above, ask your doctor or pharmacist for advice before taking this medicine.

### Tentin with alcohol

Alcohol must not be consumed while taking this medicine. Remember that some foods and medicines contain alcohol.

### Pregnancy and breast-feeding

Tentin may affect an unborn baby.

If your daughter is pregnant or breast-feeding, she may be pregnant or is planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

- your doctor will discuss contraception
- if your daughter is pregnant she may have to stop taking this medicine.
- it is possible that this medicine is passed into human breast milk. Therefore, your doctor will decide whether your daughter should stop breast-feeding or stop taking this medicine.

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### Driving and using machines

Your child may feel dizzy, have problems focussing, or have blurred vision when taking this medicine. If so, it may be dangerous to do things such as drive, use machines, ride a bike or horse, or climb trees.

### Tentin contains isomalt (E953)

If you have been told by your doctor that your child cannot tolerate some sugars, talk to your doctor before using this medicinal product.

## 3. HOW TO TAKE TENTIN 5 mg

### How much to take

Always use this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The normal recommended dose is between 5 mg and 20 mg.

- Your doctor will usually start treatment with a low dose of one tablet Tentin. This will be increased gradually by one tablet Tentin at weekly intervals, as required.
- The maximum daily dose is 20 mg (in rare cases, 40 mg may be needed).

### How to take

The medicinal product is intended for oral use.

Your child should take Tentin tablets with a drink of water, preferably with or immediately after meals. Tentin tablets should be taken at the same time in relation to the meals. The last dose should, in general, not be given too late after lunch in order to prevent disturbances in falling asleep.

The tablets have a score line and can be divided, if needed. The score line is only there to help you break the tablet if there is difficulty swallowing it whole. To split it, place the tablet onto a hard surface with the cross-scored, smooth side downwards and then push carefully with your index finger at the centre of its top side. The tablet then breaks into four parts.

If your child does not feel better, tell your doctor. They may decide a different treatment is needed.

### Long-term treatment

Your doctor will decide how long the treatment is given. If your child takes this medicine for more than a year, your doctor should stop treatment for a short time, e.g. during a school holiday. This will show if the medicine is still needed.

### Not using Tentin properly

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

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

### **If your child takes more Tentin than they should**

Talk to a doctor or call an ambulance straight away. Tell them how much has been taken. Show the package or this leaflet to the doctor. Overdosage of these tablets can be very serious.

Signs of overdose may include: excitement, hallucinations, convulsions leading to coma, irregular and rapid heartbeat, and reduced breathing.

### **If your child forgets to take Tentin**

Do not use a double dose to make up for a forgotten dose. If your child forgets a dose, wait until it is time for the next dose.

### **If your child stops taking Tentin**

If your child suddenly stops taking this medicine, this can lead to extreme tiredness, depression, mood disorders, agitation, sleep disturbances, increased appetite, or involuntary movements. Your doctor may want to gradually reduce the amount of medicine taken each day, before stopping it completely. Talk to your doctor before stopping Tentin.

**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, but not everybody gets them. Your doctor will talk to you about these side effects.

### **Very common: may affect more than 1 in 10 people**

- decreased appetite, reduced weight gain and weight loss during prolonged use in children
- difficulty in sleeping
- nervousness

### **Common: may affect up to 1 in 100 people**

- irregular or increased heartbeat, a more noticeable heartbeat,
- abdominal pain and/or cramps, nausea, vomiting, dry mouth  
These effects usually occur at the beginning of treatment and may be alleviated by taking the medicine with meals.
- changes in blood pressure and heart rate (usually increases)
- joint pain
- A feeling of dizziness or “spinning”, jerky or involuntary movements, headache, hyperactivity
- abnormal behaviour, aggression, excitation, anorexia, anxiety, depression, irritability

### **Rare: may affect up to 1 in 1,000 people:**

- angina pectoris
- difficulties in visual sharpening and focus, blurred vision, dilation of the pupils.
- reduced height increase during prolonged use in children

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- fatigue
- rash, hives

### **Very rare: may affect up to 1 in 10,000 people**

- Reduction in red blood cells which can make the skin pale and cause weakness or breathlessness, changes in blood cell counts (leukopenia, thrombocytopenia, thrombocytopenic purpura)
- cardiac arrest
- Tourette's syndrome
- abnormal liver function ranging from hepatic enzyme elevations to hepatic coma
- muscle cramps
- convulsions, involuntary movements (choreoathetoid movements), bleeding inside the skull (intracranial haemorrhage)
- hallucinations, psychosis / psychotic reactions, suicidal behaviour or suicide, tics, worsening of pre-existing tics
- itchy red skin lesions (erythema multiforme) or scaly skin patches (exfoliative dermatitis), recurring rash, which happens in the same place each time the medicine is taken (fixed drug eruption)
- inflammation of the blood vessels of the spinal cord and brain (cerebral vasculitis) and/or occlusion

### **Not known: frequency cannot be estimated from the available data**

- heart muscle disease (cardiomyopathy), heart attack
- inflammation of parts of the large intestine when the blood flow is reduced (ischaemic colitis), diarrhoea
- chest pain, growth retardation during prolonged use, increased body temperature, allergic reactions including serious allergic reaction which causes swelling of the face or throat (angioedema) and serious allergic reaction which causes difficulty in breathing or dizziness (anaphylaxis), sudden death
- disturbance of the acid-base balance of the body (acidosis)
- abnormal muscle breakdown which can lead to kidney problems (rhabdomyolysis)
- difficulty in controlling movements (ataxia), dizziness, abnormal or impaired sense of taste, concentration difficulties, hyperreflexia, stroke, shaking (tremor)
- confusion, dependence, dysphoria, emotional instability, euphoria, impaired cognitive test performance, altered libido, night terrors, obsessive-compulsive behaviour, panic states, paranoia, restlessness
- renal damage
- impotence
- sweating, hair loss
- circulatory failure

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance  
Earlsfort Terrace  
IRL - Dublin 2  
Tel: +353 1 6764971  
Fax: +353 1 6762517  
Website: [www.hpra.ie](http://www.hpra.ie)  
E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

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By reporting side effects you can help provide more information on the safety of this medicine.

### 5. HOW TO STORE TENTIN

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 and the box after “EXP”. The expiry date refers to the last day of that month.

Do not store above 30 °C.

Store in the original package 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 to protect the environment.

### 6. CONTENTS OF THE PACK AND OTHER INFORMATION

#### What Tentin 5 mg contains:

- The active substance is dexamfetamine sulphate  
One tablet contains 5 mg dexamfetamine sulphate
- The other ingredients are:  
isomalt (E953)  
crospovidone  
magnesium stearate

#### What Tentin 5 mg looks like and the contents of the pack:

##### Tentin 5 mg tablets

White, round, cloverleaf-shaped tablets with a notched, cross-scored line on the top side and a cross-scored line embossed with “S” on each quarter on the rear side.

The tablets can be divided.

Pack sizes: 20, 30, 50, or 100 tablets

Boxes containing tablets packed in blisters made of PVC/PE/PVdC aluminium foil

Not all pack sizes may be marketed.

#### Marketing authorisation holder and manufacturer

MEDICE Arzneimittel Pütter GmbH & Co. KG  
Kuhloweg 37  
58638 Iserlohn  
Germany

**This package leaflet was last revised in 01/2016**

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

Ireland: Tentin 5 mg tablets

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Denmark:	Attentin 5 mg
Finland:	Attentin 5 mg
Luxembourg:	Attentin 5 mg
Netherlands:	Amfexa 5 mg
Norway:	Attentin 5 mg
Spain:	Amfexa 5 mg comprimidos
Sweden:	Attentin 5 mg
United Kingdom:	Amfexa 5 mg Tablet

This package leaflet is also available in formats appropriate for the blind and partially sighted.