

## **B. PACKAGE LEAFLET**

## **Package leaflet: Information for the user**

<b>Catapresan TTS-1</b>	<b>2.5 mg transdermal patches</b>
<b>Catapresan TTS-2</b>	<b>5 mg transdermal patches</b>
<b>Catapresan TTS-3</b>	<b>7.5 mg transdermal patches</b>

clonidine

**Read all of this leaflet carefully before you start using 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 Catapresan TTS is and what it is used for
2. What you need to know before you use Catapresan TTS
3. How to use Catapresan TTS
4. Possible side effects
5. How to store Catapresan TTS
6. Contents of the pack and other information

#### **1. What Catapresan TTS is and what it is used for**

Catapresan TTS contains the active substance clonidine, which works by reducing high blood pressure regardless of the cause.

Catapresan TTS is a patch that is applied onto the skin, through which the active ingredient enters the body.

Catapresan TTS is indicated for adults in the treatment of high blood pressure. Catapresan TTS can be used alone or in combination with other blood pressure lowering medicines.

You must talk to a doctor if you do not feel better or if you feel worse.

#### **2. What you need to know before you use Catapresan TTS**

##### **Do not use Catapresan TTS**

- if you are allergic to clonidine or any of the other ingredients of this medicine (listed in section 6).
- If you suffer from severe bradyarrhythmia (slow and irregular heartbeat) caused by sinus node disease or second or third degree atrioventricular block (heart rhythm disturbances).

##### **Warnings and precautions**

Talk to your doctor or pharmacist before using Catapresan TTS.

Use Catapresan TTS with caution:

- if you suffer from mild to moderate bradyarrhythmia such as decreased sinus rhythm (heart rhythm disturbances)
- if you suffer from Raynaud's disease (spasm of the arteries in the fingers and toes)
- if you have disorders involving changes in blood transport in the body, including the brain
- if you suffer from depression
- if you suffer from polyneuropathy (a disease characterized by a gradual and progressive loss of muscle strength and/or changes in sensation in the arms and legs)
- if you suffer from constipation.

#### If you suffer from pheochromocytoma

In case of hypertension caused by pheochromocytoma (disease that causes substances that increase blood pressure to be released in the body), the use of Catapresan TTS has not shown any effectiveness.

#### If you have reduced kidney function (renal failure)

If you suffer from renal failure (i.e. reduced kidney function) the dosage of Catapresan TTS must be carefully defined by your doctor according to your condition (see paragraph 3. “How to use Catapresan TTS”).

#### If you have reduced heart function (heart failure or severe coronary artery disease)

If you suffer from severe heart disease (heart failure or severe coronary artery disease), your treatment with Catapresan TTS should be monitored particularly carefully, as with other blood pressure lowering medicines.

#### In case of surgery

In case you have to undergo surgery, treatment with Catapresan TTS should not be suspended during surgery.

Cases in which it may be necessary to temporarily remove the patch:

- consult your doctor immediately if you intend to remove the patch because you have noticed moderate to severe local skin irritation and/or blistering (collection of fluid under the skin) at the patch application site or a generalized-type skin rash (see section 4. “Possible side effects”)
- if you notice an isolated and minor local skin irritation within 7 days of patch application, you can remove the patch and replace it with a new one, applying it to another area of the skin
- you must remove the patch before undergoing electrical stimulation of the heart to restore normal heart rhythm (such as in defibrillation or cardioversion surgery), as this may increase the risk of a phenomenon associated with the use of defibrillators called arcing. Therefore, in this case consult your doctor to define whether and how to continue the therapy
- Catapresan TTS contains aluminium, therefore you must remove the patch before undergoing an MRI scan as burns have been reported at the site of application of the patch during MRI scans. Therefore, in this case consult your doctor who will decide when to reapply the patch.

#### Contact lenses

Treatment with Catapresan TTS may cause reduction in lacrimation, which should be taken into account if you use contact lenses.

#### **Children and adolescents**

Use in children and adolescents under 18 years of age is not recommended, as safety and efficacy have not been established.

Although Catapresan TTS is not recommended in children and adolescents, if your doctor does prescribe it for your child, bear in mind that the use of clonidine in children and adolescents under 18 years of age in combination with methylphenidate (a medicine used in children to treat attention deficit hyperactivity disorder) can cause serious undesirable effects, including death. Therefore, the use of clonidine in this combination is not recommended.

#### **Other medicines and Catapresan TTS**

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

Catapresan TTS can interact with other medicines taken at the same time, such as: other medicines used to lower blood pressure, as they increase the effect of Catapresan TTS. Your doctor may use this interaction to lower your blood pressure:

- medicines which cause an increase in blood pressure or induce a retention of sodium ions and water (such as non-steroidal anti-inflammatory drugs), as they reduce the effect of clonidine

- substances that may increase blood pressure (such as phentolamine or tolazoline), as they may inhibit the effects of clonidine
- substances that slow down the rhythm or rate of the heart (such as beta-blockers or digitalis glycosides), as they can cause or enhance heart rhythm disturbances in bradycardia (condition in which there is a reduction in the number of beats of the heart heart per minute)
- concomitant administration of a beta-blocker may cause or potentiate peripheral vascular dysfunction (disorders of the peripheral blood vessels)
- antidepressants (such as tricyclic antidepressants or neuroleptics), as they may decrease or eliminate the effect of Catapresan TTS and may cause or aggravate blood pressure regulation disorders
- medicines that affect the central nervous system by reducing its activity, as clonidine may enhance their effect.

### **Catapresan TTS with food, drink and alcohol**

Alcohol effects may be enhanced by clonidine, therefore the use of alcohol during treatment with clonidine is not recommended.

### **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.

#### Pregnancy

No adequate studies have been conducted in pregnant women.

Like all other medicinal products, Catapresan TTS should only be administered during pregnancy when absolutely necessary. In this case the doctor should closely monitor both mother and child.

Clonidine crosses the placental barrier and can slow down the heart rate of the baby.

There is inadequate experience regarding the long-term effects of prenatally exposure to the medicinal product. During pregnancy, oral clonidine medicinal products are preferable.

Intravenous administration of clonidine should be avoided.

Animal studies have shown no harmful effects on the fetus.

A transient increase in postpartum blood pressure in the newborn cannot be excluded.

#### Breast-feeding

Due to lack of sufficient data, the use of Catapresan TTS during breastfeeding is not recommended.

#### Fertility

No studies on the effects on human fertility have been conducted. The available studies have not shown direct or indirect harmful effects with regard to fertility.

### **Driving and using machines**

No studies have been conducted to evaluate the effects on the ability to drive and use machines.

However, during treatment with Catapresan TTS, the following possible undesirable effects may occur: vertigo (dizziness), sedation and accommodation disorders (difficulty focusing images) (see paragraph 4 "Possible side effects"). Therefore, be cautious when driving vehicles or using machines. If you experience any of the above undesirable effects, potentially hazardous activities, such as driving or using machines, must be avoided.

## **3. How to use Catapresan TTS**

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

#### Adults

Treatment with Catapresan TTS should be initiated with Catapresan TTS-1 2.5 mg transdermal patch, applying the patch once every 7 days. The doctor must define the dosage according to the individual therapeutic needs.

If after 1 to 2 weeks the reduction in blood pressure is not sufficient, your doctor may increase the dosage by adding another 2.5 mg patch or using Catapresan TTS-2 5 mg transdermal patch. An increase in dosage above two 7.5 mg Catapresan TTS-3 patches is not usually accompanied by an increase in efficacy.

When Catapresan TTS is applied for the first time as a replacement for oral treatment with clonidine hydrochloride or other blood pressure lowering medicines, the effect of Catapresan TTS transdermal patch may not be achieved for 2-3 days. Therefore, your doctor may gradually reduce the dose of the medicine you are taking.

Especially in more severe forms of high blood pressure, your doctor may decide to keep some or all of the previous treatments you were taking to lower your blood pressure.

*If you have reduced kidney function (renal impairment)*

The dose should be defined by the doctor both as a function of individual response and as a function of the degree of impairment of renal function.

Continuous monitoring of your kidney function by your doctor is necessary.

If you are on dialysis: Your usual dialysis removes only small amounts of clonidine from your blood, so you do not need to take further doses of clonidine after you have dialysis.

**Instructions for use (how to apply the patch)**

The patch must be applied to an area of intact, hairless skin on the upper thorax (chest) or upper outer arm, once every 7 days. Each new patch application must take place on a different area of skin from the previous patch. Before applying the patch, you must remove the two parts of the transparent film that protects the adhesive layer of the patch. If the patch starts to loosen during the 7 days of application, you must apply the adhesive cover patch directly onto the patch itself to ensure good adhesion (see below “How to use the adhesive overlay patch”).

Rare cases have been reported where it was necessary to change the patch before the 7 days to maintain control of blood pressure.

- 1) Apply one Catapresan TTS transdermal patch every 7 days, on the same day of the week.
- 2) Choose an application area that is hairless (for example the outer arm or upper chest) (fig. 1).

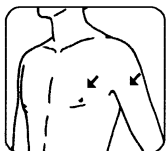


Fig. 1

The chosen skin area must be free of cuts, abrasions (wounds, skin lesions), irritations, calluses and scars and must be completely dry before applying Catapresan TTS transdermal patch.

It is advisable not to apply Catapresan TTS transdermal patch onto skin folds or in areas where it could be constricted by clothing, to avoid premature detachment of the patch itself.

- 3) Wash your hands and dry them thoroughly before removing the patch from the packaging.
- 4) Wash the chosen area with soap and water only, and dry it carefully.
- 5) Open the sachet labelled “Catapresan TTS (clonidine)” (fig. 2) and remove the patch.

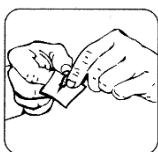


Fig. 2

- 6) Remove both parts of the transparent film from the center of the patch without touching the medicated side with your hands (fig. 3).

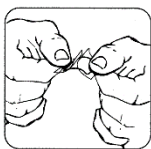


Fig. 3

- 7) Apply the Catapresan TTS transdermal patch onto the chosen area of skin by applying light pressure around the edges (fig. 4).  
Wash your hands immediately after application.



Fig. 4

- 8) After 7 days, remove the old patch and apply a new one onto a different area of skin, repeating the procedure from step 2 onwards.

#### What to do if the patch comes off

If the patch detaches from the skin before 7 days, you must use the overlay patch.

*Warning: the adhesive overlay patch does not contain any medicine and should not be used alone.*

The adhesive overlay patch should be applied directly over the Catapresan TTS transdermal patch only if the transdermal patch starts loosening from skin.

#### How to use the adhesive overlay patch

- 1) Wash your hands with soap and water and dry them carefully
- 2) Use a dry cloth to wipe around the area where Catapresan TTS transdermal patch is applied and with light pressure ensure that the edges of the Catapresan TTS transdermal patch are in contact with the skin.
- 3) Open the sachet labelled "Adhesive overlay patch " and remove the protective plastic film.
- 4) Apply the adhesive overlay patch by pressing gently, especially around the edges, directly on top of the Catapresan TTS transdermal patch, taking care to position the adhesive overlay patch centrally over the Catapresan TTS transdermal patch (fig.5).



Fig. 5

#### **Use in children and adolescents**

Use in children and adolescents under 18 years of age is not recommended as safety and efficacy have not been established.

#### **If you use more CatapresanTTS than you should**

##### Symptoms

In case of clonidine overdose, the following may occur: general depression of the central nervous system with consequent constriction of the pupil (reduction in the size of the pupil), lethargy (a state of deep sleep with reduced response to normal stimuli), bradycardia (reduction of the of heart beats per minute), hypotension (low blood pressure), hypothermia (low body temperature), somnolence up to

coma, respiratory depression including apnoea. You may also experience unexpected increase in blood pressure (paradoxical hypertension).

Rarely, cases of Catapresan TTS poisoning due to accidental or intentional ingestion of patches have been reported. Most of these cases involve children.

#### Treatment

If you use too much Catapresan TTS you must remove all patches and notify your doctor immediately or go to the nearest hospital.

#### **If you forget to use or change Catapresan TTS**

Do not use a double dose to make up for a missed dose.

If you forget to change your patch when you are supposed to, you should replace it as soon as possible, by applying the new patch according to the dosage prescribed by your doctor.

#### **If you stop using Catapresan TTS**

- You should not stop treatment with Catapresan TTS unless after consulting your doctor, as the sudden interruption of high dose and long term treatment with Catapresan TTS can cause restlessness (agitation), palpitations (feeling of increased heartbeat), rapid increase in blood pressure, nervousness, tremors, headache (headache) or nausea. In case an interruption of treatment with Catapresan TTS is necessary, your doctor will gradually reduce the dose over a period of 2 - 4 days.
- Contact your doctor immediately if you experience excessive increase in blood pressure after discontinuation of treatment with Catapresan TTS.
- If you have experienced a local skin rash after using the Catapresan TTS patch and have had to switch to oral clonidine treatment, this switch may lead to the development of a generalized skin rash.

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.

Most side effects experienced during treatment with Catapresan TTS were mild and tended to regress upon continuation of treatment.

The side effects are listed below according to frequency:

##### **Very common (may affect more than 1 in 10 patients)**

- vertigo (dizziness)
- sedation (physical and mental relaxation)
- orthostatic hypotension (reduction in blood pressure when standing up accompanied by symptoms such as dizziness/light-headedness)
- dry mouth
- erythema (redness of the skin) at the application site.

##### **Common (may affect up to 1 in 10 people)**

- depression
- sleep disorders
- cephalgia (headache)
- drowsiness
- constipation
- nausea
- salivary gland pain (glands found in the mouth, face and neck)
- vomiting
- site irritation
- application site burning

- application site discolouration
- erectile dysfunction
- application site pain
- fatigue

#### **Uncommon (may affect up to 1 in 100 people)**

- confusional state
- delusional perception (abnormal interpretation of reality)
- hallucinations (perception of things that do not exist in reality)
- decreased libido (reduced sex drive)
- nightmares
- paraesthesia (numbness and tingling sensation in the legs, arms or other parts of the body)
- accommodation disorders (difficulty focusing images)
- bradyarrhythmia, sinus bradycardia (slow and irregular heartbeat)
- Raynaud's syndrome (disease due to impaired blood circulation)
- presence of small skin bumps (papules) at the application site
- dermatitis (inflammation of the skin) at the application site
- urticaria (redness of the skin accompanied by itching)
- itching
- rash (skin eruptions)
- malaise.

#### **Rare (may affect up to 1 in 1.000 people)**

- reduction of lacrimation
- atrioventricular block (difficulty of the heart to pump blood around the body due to disturbances in the electrical conduction system of the heart)
- dryness of the nasal mucosa
- colonic pseudo-obstructions (intestinal disease characterized by slowed intestinal transit and reduced ability to push food through the intestine)
- hair loss (alopecia)
- gynaecomastia (breast enlargement)
- increase in glycaemia (blood sugar).

#### **Reporting of side effects**

If you get any side effects, including any ones not listed in this leaflet, talk to your doctor or pharmacist. You can also report side effects directly via the national reporting system at <https://www.aifa.gov.it/content/segnalazioni-reazioni-avverse>. By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store Catapresan TTS**

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

This medicine does not require any special storage conditions.

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

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

### **6. Contents of the pack and other information**

#### **What Catapresan TTS contains**

Catapresan TTS is a clonidine-based transdermal patch which provides a continuous and constant systemic release of the active ingredient for 7 days.

The package consists of rectangular patches with rounded corners; the adhesive side is opaque white covered with two overlapping transparent protective liners; the non-adhesive side is light brown with a diagonal print showing the name of the active substance followed by TTS-1 or TTS-2 or TTS-3 and the company logo.

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**CATAPRESAN TTS-1 2.5 mg transdermal patches** (surface area of 3.5 cm<sup>2</sup>)

- The active substance is: clonidine 2.5 mg (programmed for in vivo delivery of 0.1 mg of clonidine a day for 7 days).
- The other excipients are: light mineral oil; high molecular weight polyisobutylene; medium molecular weight polyisobutylene; silicon dioxide colloidal.  
Film constituents: medium density polyethylene, aluminium-polyester/ethylene vinyl acetate copolymer; polypropylene film; fluorocarbon diacrylate-coated/polyester film

**CATAPRESAN TTS-1 2.5 mg transdermal patches** (surface area of 7.0 cm<sup>2</sup>)

- The active substance is: clonidine 5 mg (programmed for in vivo delivery of 0.2 mg of clonidine a day for 7 days).
- The other excipients are: light mineral oil; high molecular weight polyisobutylene; medium molecular weight polyisobutylene; silicon dioxide colloidal.  
Film constituents: medium density polyethylene, aluminium-polyester/ethylene vinyl acetate copolymer; polypropylene film; fluorocarbon diacrylate-coated/polyester film

**CATAPRESAN TTS-3 7.5 mg transdermal patches** (surface area of 10.5 cm<sup>2</sup>)

- The active substance is: clonidine 7.5 mg (programmed for in vivo delivery of 0.3 mg of clonidine a day for 7 days).
- The other excipients are: light mineral oil; high molecular weight polyisobutylene; medium molecular weight polyisobutylene; silicon dioxide colloidal.  
Film constituents: medium density polyethylene, aluminium-polyester/ethylene vinyl acetate copolymer; polypropylene film; fluorocarbon diacrylate-coated/polyester film

**What Catapresan TTS looks like and contents of the pack**

For all dosages, the pack contains 2 transdermal patches + 2 overlay patches, each individually packaged in a sachet.

**Marketing Authorisation Holder**

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**Manufacturer responsible for batch release**

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