ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

HYPERIUM 1 mg, tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Rilmenidine dihydrogen phosphate ..... 1.544 mg

Corresponding to rilmenidine base ..... 1.000 mg

For one tablet.

Excipient: lactose.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Hypertension.

4.2. Posology and method of administration

The recommended dosage is 1 tablet daily as a single morning dose.

In the event of insufficient results after one month of treatment, the dosage may be increased to 2 tablets daily in 2 doses (one in the morning and one in the evening) at the beginning of meals.

Given its good clinical and biological acceptability, Hyperium may be administered to elderly and diabetic hypertensive patients.

In patients with renal insufficiency, no dosage adjustment is necessary in principle if the creatinine clearance is greater than 15 mL/min.

Treatment must be continued indefinitely.

Paediatric population

Due to the lack of data, the use of Hyperium in children is not recommended.

4.3. Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Severe depression.
- Severe renal insufficiency (creatinine clearance < 15 mL/min).

4.4. Special warnings and precautions for use

Do not discontinue treatment suddenly, but reduce the dosage gradually.

Like all antihypertensive agents, in patients with a recent history of vascular disorders (stroke, myocardial infarction), Hyperium should be administered under regular medical supervision.

The consumption of alcohol is not recommended during treatment (see section 4.5).

The use of Hyperium in combination with beta-blockers administered in heart failure is not recommended (see section 4.5).

Because of the possibility of orthostatic hypotension, older patients should be advised of the increased risk of falling.

The use of Hyperium in combination with sodium oxybate is not recommended (see section 4.5).

This medicine contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5. Interaction with other medicinal products and other forms of interaction

Concomitant use not recommended (see section 4.4)

+ Alcohol (drink or excipient)
Alcohol increases the sedative effect of these substances. Impaired vigilance may render driving of vehicles and use of machinery dangerous. Alcoholic beverages and medicines containing alcohol should be avoided.

+ Beta-blockers used in heart failure
Central reduction of sympathetic tone and vasodilator effect of centrally acting antihypertensive agents that may be harmful in patients with heart failure undergoing treatment with beta-blockers and vasodilators.

+ Sodium (oxybate)
Increased central depression. Impaired vigilance may render driving of vehicles and use of machinery dangerous.

Concomitant use which requires special care

+ Beta-blockers (excluding esmolol)
Marked increase in blood pressure in the event of abrupt discontinuation of treatment with the central antihypertensive agent.
Avoid abrupt discontinuation of the central antihypertensive agent. Clinical monitoring is required.

Concomitant use to be taken into consideration

+ Alpha-blockers for urological use (alfuzosin, doxazosin, prazosin, silodosin, tamsulosin, terazosin)

Increased hypotensive effect. Increased risk of orthostatic hypotension.

+ Alpha-blockers for antihypertensive use
Increased hypotensive effect. Increased risk of orthostatic hypotension.

+ Other sedative medicines: morphine derivatives (analgesics, antitussive agents and replacement treatments), neuroleptics, barbiturates, benzodiazepines, anxiolytics other than benzodiazepines (for example, meprobamate), hypnotics, sedative antidepressants (amitriptyline, doxepin, mianserin, mirtazapine, trimipramine), sedative H1 histamine antagonists, centrally acting antihypertensive agents, baclofen and thalidomide

Increased central depression. Impaired vigilance may render driving vehicles and operation of machinery dangerous.

+ Nitrate-like agents
Increased risk of hypotension, particularly orthostatic.

+ Medicines that can cause orthostatic hypotension
Risk of increased orthostatic hypotension.

4.6. Pregnancy and lactation

Pregnancy

There are no data or a limited amount of data (fewer than 300 pregnancy outcomes) from the use of rilmenidine in pregnant women.

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3).

As a precautionary measure, it is preferable to avoid the use of Hyperium during pregnancy.

Breastfeeding

It is unknown whether rilmenidine/metabolites are excreted in human milk.

Available pharmacodynamic/toxicological data in animals have shown excretion of rilmenidine/metabolites in milk.

A risk to newborns/infants cannot be excluded.

Hyperium should not be used during breast-feeding.

Fertility

Reproduction studies in the rat showed no effect of rilmenidine on fertility (see section 5.3).

4.7. Effects on ability to drive and use machines

No specific studies on the ability to drive and use machines have been performed.

However, considering that somnolence is a common adverse reaction, patients should be warned about their ability to drive a car or operate machinery.

4.8. Undesirable effects

Summary of the safety profile

At the dose of 1 mg in a single daily administration, during controlled studies, the incidence of undesirable effects was comparable to that observed with placebo.

At a dose of 2 mg of HYPERIUM daily, the controlled comparative studies versus clonidine at a dose of 0.15 to 0.30 mg/day or alpha-methyldopa at a dose of 500 to 1000 mg/day showed that the incidence of undesirable effects was significantly lower than that observed with clonidine or alpha-methyldopa.

Tabulated list of adverse reactions

The following undesirable effects or events have been reported and ranked using the following frequency: Very common (≥1/10), Common (≥1/100, <1/10), Uncommon (≥1/1 000, <1/100), Rare (≥1/10 000, <1/1 000), Very Rare: (< 1/10 0000), not known (cannot be estimated from the available data).

System Organ Class	Frequency	Preferred term
Psychiatric disorders	Common	Anxiety
		Depression
		Insomnia
Nervous system disorders	Common	Somnolence
		Headache
		Dizziness
Cardiac disorders	Common	Palpitations
Vascular disorders	Common	Peripheral coldness
	Uncommon	Hot flushes
		Orthostatic hypotension
Gastrointestinal disorders	Common	Abdominal pain upper
		Dry mouth
		Diarrhoea
		Constipation
	Uncommon	Nausea
Skin and subcutaneous tissue	Common	Pruritus

System Organ Class	Frequency	Preferred term
disorders		Rash
Musculoskeletal and connective tissue disorders	Common	Muscle spasms
Reproductive system and breast disorders	Common	Sexual dysfunction
General disorders and administration site conditions	Common	Asthenia
		Fatigue
		Oedema

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system: the National agency for the safety of medicines and health products (Ansm) and the network of Regional Pharmacovigilance Centres – Website: www.ansm.sante.fr.

4.9. Overdose

Symptoms

Data related to massive ingestion are very limited. The most likely expected symptoms in this case would be marked hypotension and disorders of vigilance.

Management

The treatment must be symptomatic. In addition to gastric lavage, the recommended treatment may involve the use of sympathomimetic agents in case of marked hypotension. Hyperium is weakly dialysable.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: antihypertensive, centrally acting antiadrenergic agent, imidazoline receptor agonist, ATC code: C02AC06.

Mechanism of action

HYPERIUM 1 mg, an oxazoline compound with anti-hypertensive properties acts on both medullary and peripheral vasomotor structures. HYPERIUM 1 mg shows greater selectivity for "imidazoline" receptors than for cerebral alpha-2-adrenergic receptors, distinguishing it from reference alpha-2-agonists.

Hyperium exerts a dose-dependent antihypertensive effect in the genetically hypertensive rat. Its effects are not associated with the central neuropharmacological effects usually seen with alpha 2 agonists, except at doses higher than the antihypertensive dose in animals. In particular, the central sedative effect appears to be less marked.

Pharmacodynamic effects

This dissociation between the antihypertensive activity and neuropharmacological effects has been confirmed in man. Hyperium exerts a dose-dependent antihypertensive activity on the systolic and diastolic blood pressure in both the erect and supine positions. At therapeutic doses (1 mg per day as a single administration or 2 mg per day in divided doses), double-blind studies versus placebo and reference product have demonstrated the antihypertensive efficacy of Hyperium in mild to moderate hypertension. This efficacy is maintained throughout the 24-hour period and on exercise. These results have been confirmed over the long-term, without the development of tolerance.

With the dose of 1 mg per day, double-blind placebo controlled studies have shown that Hyperium does not affect tests of alertness. The incidence of side-effects (drowsiness, dryness of the mouth, constipation) was no different than that seen with placebo.

With the dose of 2 mg per day, double-blind studies versus a reference alpha-2-agonist administered at an equihypotensive dose demonstrated that the incidence of side-effects, and the severity of these effects were significantly lower with Hyperium.

- At therapeutic doses, Hyperium has no effect on cardiac function, does not cause salt and water retention and does not disturb metabolic equilibrium:
    - Hyperium continues to exert significant antihypertensive activity 24 hours after administration, with a reduction in total peripheral resistance, but no change in cardiac output. Indices of contractility and cardiac electrophysiology are not affected.
    - Hyperium does not cause postural hypotension (particularly in the elderly) and does not interfere with the physiological increase in heart rate on exercise.
    - Hyperium does not induce any changes in renal blood flow, glomerular filtration rate or filtration fraction, and does not affect kidney function.
    - Hyperium spares glucose metabolism (including that of diabetic subjects, whether insulin or non-insulin dependent), and does not affect lipid metabolism.

5.2. Pharmacokinetic properties

Absorption:

- is rapid: the peak plasma concentration (3.5 ng/mL) is reached 1.5 to 2 hours following absorption of a single dose of 1 mg of Hyperium;
- is complete: the absolute bioavailability is 100 %, there is no hepatic first-pass effect;
- is consistent: interindividual variation is not marked, and concomitant food consumption does not affect the bioavailability. There is no variation in absorption levels at the recommended therapeutic doses.

Distribution

Protein binding is less than 10%. The volume of distribution is 5 L/kg.

Metabolism

Hyperium is only very slightly metabolised. The metabolites are found in trace amounts in the urine and result from the hydrolysis or oxidation of the oxazoline ring. These metabolites are devoid of alpha 2 agonist activity.

Elimination

Hyperium is essentially eliminated by the kidney: 65 % of the dose administered is excreted unchanged in the urine. Renal clearance represents two thirds of total clearance.

The elimination half-life is 8 hours. This is not affected by the dose administered nor by repeated administration. The pharmacological duration of action is longer, significant antihypertensive activity being maintained to 24 h after administration in hypertensive patients treated with a dose of 1 mg per day.

Repeated administration: steady state is attained at 3 days ; study of plasma levels has shown that they remain stable over 10 days.

Long-term monitoring of plasma levels in hypertensive patients (treatment for 2 years) has established that plasma levels of Hyperium remain stable.

In elderly subjects

Pharmacokinetic studies in elderly patients (over 70 years old) have demonstrated an elimination half-life of 12 hours.

In subjects with hepatic insufficiency

The elimination half-life is 11 hours.

In subjects with renal insufficiency

As a result of the essentially renal elimination of the drug, a reduction in the rate of elimination is observed proportional to the severity of the renal insufficiency. In patients with severe renal insufficiency (creatinine clearance less than 15 mL/min), the elimination half-life is approximately 35 hours.

5.3. Preclinical safety data

Non-clinical data from studies of acute toxicity, repeated dose toxicity, genotoxicity/mutagenicity, carcinogenic potential and reproductive toxicity have shown no particular risk for humans.

Undesirable effects on peri- and post-natal development (reduced birth weight) have only been observed at doses toxic for the mother.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Lactose, microcrystalline cellulose (avicel pH 102), paraffin, sodium starch glycolate, colloidal silica (aerosil 200), magnesium stearate, talc, white beeswax.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

2 years.

6.4. Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5. Nature and contents of container

10, 15, 20, 30, 90, 100 tablets in blister packs (Polyamide/PVC/Aluminium).

6.6. Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

LES LABORATOIRES SERVIER
50, rue Carnot
92284 SURESNES Cedex
France

8. MARKETING AUTHORISATION NUMBER(S)

- 329 422-6: 10 tablets in blister packs (Polyamide/PVC/Aluminium).
- 329 423-2: 15 tablets in blister packs (Polyamide/PVC/Aluminium).
- 329 468-6:20 tablets in blister packs (Polyamide/PVC/Aluminium).
- 329 469-2:30 tablets in blister packs (Polyamide/PVC/Aluminium).
- 372 257-3:90 tablets in blister packs (Polyamide/PVC/Aluminium).
- 558 338-3:100 tablets in blister packs (Polyamide/PVC/Aluminium).

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23/04/1987

Date of latest renewal: 24/04/2012

10. DATE OF REVISION OF THE TEXT

12/05/2016

11. DOSIMETRY

Not applicable.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

GENERAL CLASSIFICATION FOR SUPPLY

List I.

ANNEX II

A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

A.1. Name and address of the manufacturer(s) of the biological active substance(s)

Not applicable.

A.2. Name and address of the manufacturer(s) responsible for batch release

LES LABORATOIRES SERVIER INDUSTRIE
905 ROUTE DE SARAN
45520 GIDY
FRANCE

B. CONDITIONS OF THE MARKETING AUTHORISATION

B.1. Conditions or restrictions regarding supply and use imposed on the marketing authorisation holder

List I.

B.2. Conditions or restrictions with regard to the safe and effective use of the medicinal product

Not applicable.

B.3. Other conditions

Not applicable.

C. SPECIFIC OBLIGATIONS TO BE FULFILLED BY THE MARKETING AUTHORISATION HOLDER

Not applicable.

D. QUALITATIVE AND QUANTITATIVE COMPOSITION OF EXCIPIENTS

Lactose ..... 47.000 mg
Microcrystalline cellulose (avicel pH 102) ..... 33.646 mg
Paraffin ..... 0.155 mg
Sodium starch glycolate ..... 4.500 mg
Colloidal silica (aerosil 200) ..... 0.230 mg
Magnesium stearate …… ..... 0.900 mg
Talc…….. ..... 2.000 mg
White beeswax ..... 0.025 mg

For one tablet.

ANNEX IIIA

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

NATURE / TYPE Outer packaging or Immediate packaging

Outer packaging.

1. NAME OF THE MEDICINAL PRODUCT

Hyperium 1 mg, tablets

Rilmenidine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Rilmenidine dihydrogen phosphate ..... 1.544 mg

Corresponding to rilmenidine base ..... 1.000 mg

For one tablet.

3. LIST OF EXCIPIENTS

Excipient with known effect: lactose.

4. PHARMACEUTICAL FORM AND CONTENTS

Tablet.

Box of 10, 15, 20, 30, 90 or 100 tablets.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.

Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Not applicable.

8. EXPIRY DATE

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Not applicable.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Not applicable.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Holder

LES LABORATOIRES SERVIER
50, rue Carnot
92284 SURESNES Cedex
France

Distributor

LES LABORATOIRES SERVIER
50, rue Carnot
92284 SURESNES Cedex
France

Manufacturer

LES LABORATOIRES SERVIER INDUSTRIE
905 ROUTE DE SARAN
45520 GIDY
France

12. MARKETING AUTHORISATION NUMBER(S)

Authorised medicine no.:

13. BATCH NUMBER

Batch {number}

14. GENERAL CLASSIFICATION FOR SUPPLY

List I.

15. INSTRUCTIONS ON USE

Not applicable.

16. INFORMATION IN BRAILLE

In accordance with the regulations in force.

PICTOGRAM TO APPEAR ON THE OUTER PACKAGING OR, IN THE ABSENCE OF OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

The pictogram must comply with the decree dated 8 August 2008 implementing article R.5121-139 of the [French] public health code and concerning the use of pictograms on the outer packaging of certain medicines and products.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

NATURE/TYPE Blisters/Strips

Blister pack.

1. NAME OF THE MEDICINAL PRODUCT

HYPERIUM 1 mg, tablet

Rilmenidine

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder

LES LABORATOIRES SERVIER

Distributor

LES LABORATOIRES SERVIER

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

Batch {number}

5. OTHER

Not applicable.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

NATURE/TYPE Small immediate packaging units

Not applicable.

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Not applicable.

2. METHOD OF ADMINISTRATION

Not applicable.

3. EXPIRY DATE

Not applicable.

4. BATCH NUMBER

Not applicable.

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

Not applicable.

6. OTHER

Not applicable.

ANNEX IIIB

PACKAGE LEAFLET: INFORMATION FOR THE USER

Name of the medicinal product

HYPERIUM 1 mg, tablet

Rilmenidine

Boxed text

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

Leaflet contents

In this leaflet:

1. WHAT HYPERIUM 1 mg, tablets IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group

Pharmacotherapeutic group: antihypertensive, ATC code: C02AC06.

Therapeutic indications

Hyperium is recommended in the treatment of hypertension.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE HYPERIUM 1 mg, tablets

List of information necessary before taking the medicinal product

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

Contraindications

Do not take HYPERIUM 1 mg, tablets:

- If you are allergic (hypersensitive) to rilmenidine or any of the other ingredients of this medicine (listed in section 6).
- If you have severe depression.
- If you have severe renal insufficiency.

Precautions for use; special warnings

Warnings and precautions

Never stop the treatment abruptly; your doctor will gradually reduce the dosage.

Tell your doctor if you have recently had a cardiovascular event (stroke, myocardial infarction). This treatment should be taken under regular medical supervision.

If you are elderly, your blood pressure may drop when you stand, leading to a risk of falling.

This medicine contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Talk to your doctor, pharmacist or nurse before taking Hyperium 1 mg, tablets.

Children and adolescents

HYPERIUM must not be used in children or adolescents.

Interactions with other medicinal products

Other medicines and HYPERIUM 1 mg, tablets

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

Tell your doctor if you are taking any of the following medicines, as their combination with Hyperium is not recommended:

- beta-blockers used to treat heart failure,
- sodium oxybate (used to treat narcolepsy)

Tell your doctor if you are taking any of the following medicines, as special care may be necessary:

- beta-blockers, except esmolol (used to treat hypertension and angina, a condition that causes chest pain),
- tricyclic antidepressants (used to treat depression).

Tell your doctor if you are taking any of the following medicines, as their combination with Hyperium must be taken into consideration:

- alpha-blockers for urological use (alfuzosin, doxazosin, prazosin, silodosin, tamsulosin, terazosin),
- alpha-blockers for antihypertensive use,
- other sedative medicines that may impair vigilance when taken with Hyperium: morphine derivatives (analgesics, antitussive agents and replacement treatments), medicines used to treat anxiety and difficulty sleeping (benzodiazepines, anxiolytics other than benzodiazepines, hypnotics, neuroleptics, barbiturates), H1 antihistamines (used to treat allergies and allergic reactions), medicines used to treat depression (amitriptyline, doxepin, mianserin, mirtazapine, trimipramine), other centrally acting antihypertensive agents used to treat hypertension, baclofen (used to treat muscle stiffness occurring in diseases such as multiple sclerosis, thalidomide (used to treat certain cancers),
- nitrate-like medicines (used to treat angina attacks and heart failure), which may lead to a fall in blood pressure when standing up,
- medicines which may lead to a fall in blood pressure when standing up.

Interactions with food and drink

HYPERIUM 1 mg, tablets with food, drink and alcohol
Consumption of alcohol should be avoided during treatment.

Interactions with herbal therapy products or alternative therapies

Not applicable.

Use during pregnancy and breast-feeding

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

The use of this medicine is not recommended during pregnancy.

Breastfeeding

You must not take Hyperium if you are breast-feeding. Tell your doctor immediately if you are breast-feeding or about to start breast-feeding.

Sports

Not applicable.

Effects on the ability to drive and use machines

Driving and using machines

Please be aware that there is a risk of drowsiness likely to affect your ability to drive or use machines.

List of excipients with a known effect

Hyperium 1 mg, tablets contains lactose.

3. HOW TO TAKE HYPERIUM 1 mg, tablets

Instructions for a correct use

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

Posology, Method and/or route(s) of administration, Frequency of administration and Duration of treatment

Dosage

The recommended dosage is 1 tablet daily as a single morning dose.

If the response is insufficient after one month of treatment, the dosage can be increased to 2 tablets per day in 2 doses (1 tablet morning and evening) at the beginning of meals.

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

Check with your doctor, pharmacist or nurse if you are not sure.

Symptoms and instructions in case of overdose

If you take more HYPERIUM 1 mg, tablets than you should:

If you take too many tablets this may lead to further reduction in your blood pressure and impaired vigilance. Consult your doctor or pharmacist immediately.

Instructions in case of omission of one or more doses

If you forget to take HYPERIUM 1 mg, tablets:

Do not take a double dose to make up for a forgotten dose.

Risk of withdrawal syndrome

If you stop taking HYPERIUM 1 mg, tablets:

Never stop the treatment abruptly; your doctor will gradually reduce the dosage.

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

4. POSSIBLE SIDE EFFECTS

Description of side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been observed:

Common (occurring in fewer than 1 in 10 users but in more than 1 in 100 users

- anxiety, depression, insomnia,
- drowsiness, headache, dizziness,
- palpitations (awareness of your heartbeat),
- cold in the extremities (hands and/or feet),
- stomach pain, dry mouth, diarrhoea, constipation,
- skin rash, itching,

- muscle cramps,
- sexual disorders,
- weakness, fatigue, swelling (oedema).

Uncommon (occurring in fewer than 1 in 100 users but in more than 1 in 1000 users)

- hot flushes, drop in blood pressure when standing up,
- nausea.

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 the national reporting system: the National agency for the safety of medicines and health products (ANSM) and the network of Regional Pharmacovigilance Centres – Website: www.ansm.sante.fr

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

5. HOW TO STORE HYPERIUM 1 MG, TABLETS

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

Expiry date

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

Storage conditions

This medicine does not require any special storage conditions.

If necessary, warnings against certain visible signs of deterioration

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. FURTHER INFORMATION

Full list of active substances and excipients

What HYPERIUM 1 mg, tablets contains

The active substance is:

Rilmenidine dihydrogen phosphate ..... 1.544 mg

Corresponding to rilmenidine base ..... 1.000 mg

For one tablet.

The other ingredients are:

Lactose, microcrystalline cellulose (avicel pH 102), paraffin, sodium starch glycolate, colloidal silica (aerosil 200), magnesium stearate, talc, white beeswax.

Pharmaceutical form and contents

What HYPERIUM 1 mg, tablets looks like and contents of the pack

This medicine is supplied in the form of tablets.

Boxes of 10, 15, 20, 30, 90 or 100 tablets.

Not all pack sizes may be available.

Name and address of the marketing authorisation holder and manufacturing authorisation holder responsible for batch release, if different

Marketing authorisation holder

LES LABORATOIRES SERVIER
50, rue Carnot
92284 SURESNES Cedex
France

Distributor

LES LABORATOIRES SERVIER
50, rue Carnot
92284 SURESNES Cedex
France

Manufacturer

LES LABORATOIRES SERVIER INDUSTRIE
905 ROUTE DE SARAN
45520 GIDY
France

Names of the medicinal product in the Member States of the European Economic Area

Not applicable.

Date of approval of the leaflet

This leaflet was last approved on 12/05/2016.

MA under exceptional circumstances

Not applicable.

Online information

Detailed information on this medicine is available on the website of ANSM.

Information intended for healthcare professionals only

Not applicable.

Other

Not applicable.