

PRIMALAN 5MG TABLETS

(Mequitazine)

PL 05630/0028

UKPAR

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PRIMALAN 5MG TABLETS

(Mequitazine)

PL 05630/0028

LAY SUMMARY

On 21st June 2011, the MHRA granted Marketing Authorisation (licence) for the medicinal product Primalan 5mg Tablets. This medicine is only available on prescription from your doctor.

Primalan belongs to a group of medicines called antihistamines that act by blocking the body's response to histamine release and so reducing the allergic reaction.

If you come into contact with something that you are allergic to, your body responds by producing a substance called histamine. This triggers a number of different reactions in your body. These may include itchy, runny nose as in hayfever and nasal allergies (which occur at any time of the year e.g. due to animal fur or house dust mites), itchy skin conditions and allergic reactions associated with insect bites and stings.

No new or unexpected safety concerns arose from this application and it was, therefore, judged that the benefits of taking Primalan 5mg Tablets outweigh the risks; hence Marketing Authorisation has been granted.

PRIMALAN 5MG TABLETS

(Mequitazine)

PL 05630/0028

SCIENTIFIC DISCUSSION

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INTRODUCTION

MHRA granted marketing authorisation for medicinal product Primalan 5mg Tablets (PL 05630/0028) to Pierre Fabre Médicament on the 21st June 2011. This is a prescription only medicine (POM) used in the treatment of allergic conditions such as hay fever, perennial rhinitis, urticaria, pruritis of allergic origin and allergic reactions associated with insect bites and stings.

This application was submitted as abridged application according to Article 10c of Directive 2001/83/EC, cross-referring to Mequitazine 5mg Tablets (PL 00012/0161), held by May and Baker Limited, which was granted marketing authorisation on 14th December 1984.

No new data were submitted nor were they necessary for this simple application, as the data are identical to those of the previously granted cross-reference product. As the cross-reference product was granted prior to the introduction of current legislation, a public assessment report is not available for them.

A pharmacovigilance system has been provided with this application and is satisfactory.

PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 05630/0028

PROPRIETARY NAME: Primalan 5mg Tablets

COMPANY NAME: Pierre Fabre Médicament

E.C. ARTICLE: Article 10c of Directive 2001/83/EC

LEGAL STATUS: POM

1 INTRODUCTION

This is an informed consent application for Primalan 5mg Tablets, submitted under Article 10c of Directive 2001/83/EC. The application cross-refers to Mequitazine 5mg Tablets (PL 00012/0161), approved on 14th December 1984 to the marketing authorisation holder May and Baker Limited. The current application is considered valid.

2 MARKETING AUTHORISATION APPLICATION (MAA)

2.1 Name(s)

The proposed name of the product is Primalan 5mg Tablets. The product has been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

The product contains the active ingredient mequitazine.

The tablets are packed in blister packs with pack sizes of 56, 60 and 100 tablets.

And

In tablet container and bottles (Polyethylene Injection Blow Moulded HDPE) with pack sizes of 100 Tablets. The packaging and pack sizes are the same as those for the reference product.

The proposed shelf life is 3 years with storage conditions of 'Do not store above 25°C' and 'Store in the original container in order to protect from light'. These are satisfactory.

The shelf-life and storage conditions are identical to those for the reference product and are satisfactory.

2.3 Legal status

This product is prescription only medicine (POM).

2.4 Marketing authorisation holder/Contact Persons/Company

The proposed Marketing Authorisation holder is Pierre Fabre Médicament, 45, Place Abel Gance, 92100 Boulogne, France

2.5 Manufacturers

The proposed manufacturing sites are consistent with those registered for the cross referenced product and evidence of Good Manufacturing Practice (GMP) compliance has been provided.

2.6 Qualitative and quantitative composition

The proposed composition is consistent with the details registered for the cross reference product.

2.7 Manufacturing process

The proposed manufacturing process is consistent with the details registered for the cross referenced product and the maximum batch size is stated.

2.8 Finished product/shelf-life specifications

The proposed finished product and shelf-life specification is in line with the details registered for the cross referenced product.

2.9 Drug substance specification

The proposed drug substance specification is consistent with the details registered for the cross-reference product.

2.10 TSE Compliance

The magnesium stearate used has been confirmed as being of vegetable origin. The only excipient used that contains material of animal or human origin is lactose. The applicant has provided a declaration that milk used in the production of lactose is sourced from healthy animals under the same conditions as that for human consumption. None of the excipients are sourced from genetically modified organisms.

2.11 Bioequivalence

No bioequivalence data are required to support this informed consent application, as the proposed product is manufactured to the same formula utilising the same process as the cross reference product Mequitazine 5mg Tablets, PL 00012/0161.

3 EXPERT REPORTS

The applicant has included satisfactory expert reports for the application. Signed declarations and copies of the experts' CVs are enclosed for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

4. PRODUCT NAME & APPEARANCE

See 2.1 for details of the proposed product names. The appearance of the product is identical to that of the cross reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The proposed SmPC is consistent with the details registered for the cross reference product.

6. PATIENT INFORMATION LEAFLET (PIL)/LABELLING PIL

The approved PIL is satisfactory and in line with the approved SmPC. It has been prepared according to the Quality Review of Documents (QRD) template and is consistent with the details registered for the cross-reference product.

A package leaflet has been submitted to the MHRA together with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

The MAH has committed to submitting mock-ups for currently unmarketed packs to the UK regulatory authority for approval before those packs are commercially marketed.

7. CONCLUSIONS

The data submitted with the application is acceptable. The grant of marketing authorisation is recommended.

NON-CLINICAL ASSESSMENT

No new non-clinical data have been supplied with this application and none are required for applications of this type.

CLINICAL ASSESSMENT

No new clinical data have been supplied with this application and none are required for applications of this type.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The data for this application are consistent with those previously assessed for the cross reference product and, as such, have been judged to be satisfactory.

NON-CLINICAL

No new non-clinical data were submitted and none are required for applications of this type.

EFFICACY

This application is identical to the previously granted application for Mequitazine 5mg Tablets, PL 00012/0161, granted to May and Baker Limited, on 14th December 1984.

Quality, non-clinical and clinical expert statements have been provided, together with CVs showing the experts are appropriately qualified. The experts confirm that the products are identical in composition, manufacture and pharmaceutical characteristics to the respective cross reference products and that there are no toxicological or clinical issues.

No new or unexpected safety concerns arise from this application.

The SmPC, PIL and labelling are satisfactory and consistent with those for the reference product.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new non-clinical or clinical safety concerns have been identified. The applicant's product is identical to the cross reference product. Extensive clinical experience with mequitazine is considered to have demonstrated the therapeutic values of the compounds. The risk benefit is, therefore, considered to be positive.

PRIMALAN 5MG TABLETS

(Mequitazine)

PL 05630/0028**STEPS TAKEN FOR ASSESSMENT**

1	The MHRA received the marketing authorisation applications on 15 th January 1999
2	Following standard checks and communication with the applicant the MHRA considered the applications are valid on 27 th September 2007
3	Following assessment of the applications the MHRA requested further information on 16 th May 2008, 7 th July 2009, 30 th November 2009,
4	The applicant responded to the MHRA's request, providing further information on 6 th January 2009, 30 th November 2009, 9 th April 2010
5	The applications were determined on 21 st June 2011

SUMMARY OF PRODUCT CHARACTERISTICS

- 1 NAME OF THE MEDICINAL PRODUCT**
Primalan ® 5 mg Tablets
- 2 QUALITATIVE AND QUANTITATIVE COMPOSITION**
Mequitazine 5 mg
For a full list of excipients, see section 6.1
- 3 PHARMACEUTICAL FORM**
Round white or almost white tablet, 9mm diameter, flat faced bevel-edged with two score-lines on one face. The score-lines can be used to divide the tablet into equal halves.
- 4 CLINICAL PARTICULARS**
- 4.1 Therapeutic indications**
Antihistamine for the treatment of allergic conditions such as hay fever, perennial rhinitis, urticaria, pruritis of allergic origin and allergic reactions associated with insect bites and stings.
- 4.2 Posology and method of administration**
- ORAL USE**
- Adults**
One 5 mg tablet to be taken orally twice a day
- Children 12 years of age and over:** One 5 mg tablet to be taken twice a day.
- Primalan is not recommended in children under 12 years of age**
- Elderly population**
There is no information on specific dosage recommendation in the elderly. Caution should therefore be exercised in this group of patients: see section 4.4.
- Administration**
It may be preferable to take this medicine in the evening due to the possible sedative effect of mequitazine in some patient groups (the elderly).
- 4.3 Contraindications**
Hypersensitivity to mequitazine or to any of the excipients or sensitivity to phenothiazines. In patients with a history of agranulocytosis linked to the use of phenothiazines.: see section 4.8
In patients currently being treated with monoamine oxidase inhibitors (MAOIs) or those who have been treated with MAOIs within the last fourteen days (the anticholinergic properties of mequitazine are intensified by MAOIs):see section 4.5
During acute episodes of asthma: see section 4.4
Like other antihistamines mequitazine should be avoided in porphyria.
Risk of closed-angle glaucoma: see section 4.4
Risk of urine retention related to urethral or prostatic disorders: see section 4.4
- 4.4 Special warnings and precautions for use**
Cases of agranulocytosis have been described with phenothiazines. Patients should be warned that in the event of fever or an infection whilst under treatment, they should obtain medical consultation as soon as possible. In the event of marked changes to the blood count, treatment should be discontinued.
As with all antihistamines, mequitazine should be used with caution in epilepsy, asthma, prostatic hypertrophy, glaucoma, and cardiovascular or hepatic diseases:
Epileptic patients should be closely monitored because of a possible lowering of the epileptogenic threshold, known to occur with phenothiazines.
In patients with severe liver impairment there is a risk of reduced clearance and an accumulation of mequitazine.

Elderly patients are more susceptible to the side-effects of antihistamines, particularly the central nervous system depressant activity and the hypotensive effects even at therapeutic doses. Caution should therefore be exercised in this group of patients.

Avoid the consumption of alcoholic drinks and medicines containing alcohol. Impaired alertness may render driving or machine use dangerous

Caution should be exercised with sympathomimetic amines, their adrenergic effect on cardiovascular system is exacerbated.

The association with other central nervous system depressive drugs may major the central depression. Therefore, due to a possible reduced level of alertness, driving or operating machinery may be dangerous.

An enhancement of atropine undesirable effects (e.g: urinary retention, constipation, dryness of the mouth) could be observed in association with atropine and related drugs.

Because of the presence of 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

The combination of Mequitazine with other drugs is likely to exacerbate the known induced side effects of these drugs

Contraindicated: MAOIs: see section 4.3 contra-indications.

Precautions

Mequitazine may potentiate sympathomimetic amines, other antimuscarinic drugs such as atropine and tricyclic antidepressants (enhancement of antimuscarinic and sedative effects), and central nervous system depressants, including hypnotics and anxiolytics (enhancement of the sedative effect)

Alcohol. Enhancement of the sedative effects of H1 antihistamines with the use of alcohol may occur in individual patients.

4.6 Pregnancy and lactation

Pregnancy:

Animal studies have not demonstrated any teratogenic effect of mequitazine.

Insufficient relevant clinical data are available at present to assess any malformative or foetotoxic effects of mequitazine when it is administered during pregnancy.

In neonates born to mothers who have received long-term treatment with high doses of anticholinergic medicines, rare cases of digestive signs related to their atropine properties (abdominal distension, meconium ileus, delayed meconium passage, difficulties in starting feeding, tachycardia, neurological disorders, etc) have been reported.

Taking into account these data, caution should be exercised when prescribing to pregnant women. It is recommended not to use Mequitazine during the first trimester of pregnancy. It should only be prescribed if necessary thereafter, for occasional limited use during the third trimester of pregnancy.

If this medicinal product is administered towards the end of pregnancy, it is justified to ensure a period of monitoring of the neurological and digestive functions of the neonate."

Lactation:

It is unknown whether mequitazine is excreted in human breast milk.

The excretion of mequitazine in milk has not been studied in animals.

A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with Primalan 5 mg Tablets should be made taking into account the benefit of breast-feeding to the child and the benefit of Primalan 5 mg tablets therapy to the mother. In the event of lactation, use of this medicinal product may only be envisaged for brief periods (a few days).

4.7 Effects on ability to drive and use machines

In objective tests mequitazine has been shown to have no significant effect on alertness, performance and reaction time. As drowsiness can occur in some patients it is advisable to check individual responses prior to driving or operating machinery.

4.8 Undesirable effects

The most common undesirable effect with antihistamines is drowsiness / sedation. The severity varies with each patient (particularly in the elderly population). The following anticholinergic / antimuscarinic effects may also occasionally occur: dryness of the mouth, constipation, disturbance of accommodation, mydriasis, tightness in the chest, urinary retention, dysuria.

Adverse reactions reported are listed below, by organ system.

System organ class (MedDRA classification)	<i>Adverse reaction</i>
Immune system disorders	Allergic reaction related to any of the ingredients Anaphylactic shock
Blood and lymphatic system disorders	Blood dyscrasias (rare cases of agranulocytosis were described with phenothiazines)
Psychiatric disorders	Hallucinations particularly in the elderly population Nervousness
Nervous system disorders	Drowsiness Sedation: severity varies with each patient (particularly in the elderly population) Mental confusion particularly in the elderly population Agitation Excitement Insomnia Headache Psychomotor impairment Acute dyskinesia Extrapyramidal effects (reported with phenothiazine drugs)
Eyes disorders	Focusing disturbances Disturbance of accommodation Mydriasis (anticholinergic/antimuscarinic effects)
Cardiac disorders	Cardiac palpitations
Vascular disorders	Hypotension
Gastrointestinal disorders	Dryness of the mouth Constipation (anticholinergic/antimuscarinic effects)
Skin and subcutaneous tissue disorders	Photosensitivity Erythema Eczema Pruritus Purpura Urticaria Quincke's Oedema

Renal and Urinary disorders	Urinary retention Dysuria (anticholinergic/antimuscarinic effects)
General disorders and administration site conditions	Tightness in the chest

4.9 Overdose

Symptoms

Symptoms of severe overdosage have been observed: drowsiness, nausea, vomiting, anticholinergic effects, hypotension, central nervous system depression, convulsions and coma. Overdose may be fatal particularly in infants and children.

Emergency procedure

Treatment is symptomatic and supportive and may include artificial respiration, external cooling for hyperpyrexia, gastric emptying and lavage.

Diazepam may be used to control convulsion, although central nervous system depressants and other phenothiazine derivatives should be avoided.

Activated charcoal could be given. Intravenous fluids and vasopressors except adrenaline may be needed.

Antidote

There is no specific antidote.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antihistamines for systemic use

ATC code: R06AD07

Mequitazine is a phenothiazine derivative with the actions and uses of antihistamines.

Antihistamines diminish or abolish the main actions of histamine in the body by competitive, reversible blockade of histamine receptor sites on tissues; they do not inactivate histamine or prevent its synthesis or release. Antihistamines are used for palliative treatment of allergic reactions. Mequitazine is reported to cause less sedation than promethazine.

5.2 Pharmacokinetic properties

Absorption

Mequitazine is readily absorbed from the gastrointestinal tract.

Distribution

The apparent volume of distribution is high, indicating that mequitazine is extensively distributed outside the vascular compartment.

Biotransformation

Mequitazine is metabolised by the liver

Elimination

The apparent elimination half-life is 18 hours.

The excretion of mequitazine and its metabolites is principally via the bile. The amount of unchanged mequitazine in the urine is very low.

5.3 Preclinical safety data

No teratogenic effects were observed in animal studies with mequitazine.

Other preclinical effects were observed only at exposure considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose

Maize starch

Colloidal silicon dioxide E551

Magnesium stearate

Microcrystalline cellulose E460

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C.

Store in the original container in order to protect from light.

6.5 Nature and contents of container

Tablet container: 100 tablets

Bottles (Polyethylene Injection Blow Moulded HDPE): 100 tablets

Blister: 100 tablets

Blister: 60 tablets

Blister: 56 tablets

Professional Sample Pack: 6 tablets

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

Pierre Fabre Médicament

45, Place Abel Gance

92100 Boulogne

France

8 MARKETING AUTHORISATION NUMBER

PL 05630/0028

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21/06/2011

10 DATE OF PARTIAL REVISION OF THE TEXT

21/06/2011

PATIENT INFORMATION LEAFLET

PACKAGE LEAFLET:
INFORMATION FOR THE USER

Primalan® 5 mg Tablets

mequitazine

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Primalan is and what it is used for
2. Before you take Primalan
3. How to take Primalan
4. Possible side effects
5. How to store Primalan
6. Further information

1. What Primalan is and what it is used for

Primalan belongs to a group of medicines called antihistamines that act by blocking the body's response to histamine release and so reducing the allergic reaction.

If you come into contact with something that you are allergic to, your body responds by producing a substance called histamine. This triggers a number of different reactions in your body. These may include itchy, runny nose as in hayfever and nasal allergies (which occur at any time of the year e.g. due to animal fur or house dust mites), itchy skin conditions and allergic reactions associated with insect bites and stings.

If you need any further information on your condition, please ask your doctor.

2. Before you take Primalan

Tell your doctor or your pharmacist before taking your tablets if the answer to any of the following questions is « yes »:

Do not take Primalan if you:

- have ever had an allergic reaction after taking Primalan (or similar products) in the past,
- are sensitive or allergic to any of the other ingredients, particularly lactose,
- are suffering an asthma attack,
- are sensitive to phenothiazines which are usually used to treat psychiatric illness, severe agitation or anxiety,
- are taking or have taken drugs called monoamine oxidase inhibitors (MAOIs) within the last 14 days which are usually used to treat depression or Parkinson's disease,
- suffer from a condition called porphyria (a group of conditions which may be associated with abdominal symptoms such as pain and vomiting, problems with the nerves which may lead to weakness or paralysis, abnormal thoughts, skin lesions on exposure to sunlight and dark urine),
- have glaucoma (increased pressure in the eye),
- are suffering from or at risk of urinary retention (difficulty in passing urine).

Take special care with Primalan if you:

- have any liver or heart problems,
- have asthma,
- suffer from epileptic fits,
- have an enlarged prostate,
- are elderly because you are more susceptible to the side-effects, such as feeling tired, drowsy, thirsty and the hypotensive (low blood pressure) effects,
- are taking drugs called sympathomimetics which are contained in some nasal decongestants or anti-obesity medicines.

Please consult your doctor, if any of these statements are applicable to you now or at any time in the past.

If you have to go to a doctor, dentist or hospital for any reason, take all medicines with you, including Primalan.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines may interact with Primalan potentially giving unwanted side effects.

Your doctor should take special care if you are taking the following medicines as they should not be taken with Primalan:

Some drugs which are usually used to:

- treat depression (e.g. imipramine),
- treat the inability to control urination (e.g. oxybutynin),
- treat Parkinson's disease, which is a disorder of the central nervous system and is usually seen in older people with symptoms of muscle movement disorders, trembling and or slowness in movements (e.g. trihexyphenidyl, benztropine, rasagiline),
- make the airways open up and become bigger in chest disorders like asthma or chronic bronchitis (e.g. ipratropium),
- relieve nasal congestion (e.g. ephedrine),
- relieve cramps or spasms of the stomach, intestines or bladder (known as antispasmodic drugs, e.g. mebeverine),
- dilate the pupil of the eye for examination (e.g. tropicamide),
- slow down the central nervous system such as anxiolytic drugs (e.g. alprazolam) used to control anxiety and hypnotics used to induce sleep in the treatment of insomnia (e.g. zolpidem, nitrazepam).

Taking Primalan with food and drink**Consumption of alcohol:**

As Primalan may increase the sedative effects of alcohol you are advised to avoid drinking alcohol whilst taking these tablets.

Primalan can be taken with or without food.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Pregnancy

The use of Primalan in pregnant women is limited. Primalan is **NOT** recommended during the first three months of pregnancy. If necessary your doctor may prescribe Primalan for limited use during the last three months of your pregnancy. If this happens it may be necessary to monitor the effects on your new born baby.

Breast-feeding

It is unknown whether Primalan is excreted in human breast milk. As it is not known whether this is harmful to your baby, this should be discussed with your doctor whether to take this medicine or not.

Driving and using machines

As Primalan can make you drowsy, your level of alertness may be impaired making driving or machine use dangerous. Therefore, you should be responsible and assess and check your own personal responses before driving or operating machinery.

Important information about some of the ingredients of Primalan

Primalan contains a small amount of lactose (a sugar) in each tablet. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Primalan

Oral use.

You should take your tablets as your doctor has told you.

Adults:

The usual dose is one 5 mg tablet to be taken orally twice a day, although in elderly patients (over 65 years) caution should be used.

Children 12 years of age and over:

One 5 mg tablet to be taken twice a day.

Primalan is not recommended in children under 12 years of age

Due to the possible sedative effect of this medicine especially in the elderly it may be preferable to take this medicine in the evening. Your doctor will advise you.

If you take more Primalan than you should

If you accidentally take too many tablets, or if a child takes a tablet, contact your nearest hospital emergency department or tell your doctor immediately.

The main overdose symptoms are nausea, vomiting, seizure, difficulty in passing urine, constipation, mouth dryness, feeling dizzy or faint, drowsiness, sedation or coma.

If you forget to take Primalan

Do not worry, just take the tablet as soon as you remember, then continue as before. Do not take a double dose to make up a forgotten dose.

4. Possible side effects

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

All medicines can cause allergic reactions although serious allergic reactions are rare. Any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body) should be reported to a doctor immediately.

In rare cases, serious blood disorders affecting the blood cells may result causing symptoms such as fever, sore throat and painful mouth ulcers.

If you experience these, stop taking Primalan and contact your doctor immediately.

The following side effects have also been reported:

- Skin problems - itch, redness, raised wheals (nettle rash), dry eczema rash and sensitivity to sunlight/sunlamps
- Small violet spots in the skin which do not fade on pressure (purpura)
- Drowsiness, confusion and hallucinations, i.e. imagining sensations (particularly in the elderly)
- Dryness of the mouth
- Constipation
- Difficulty or pain passing urine
- Problems with vision, e.g. blurring
- Chest tightness and awareness of the heart beating (palpitations)
- Problems with co-ordination
- Muscle rigidity, tremor and/or abnormal movements
- Nervousness, agitation and excitation
- Difficulty in sleeping
- Headache
- Low blood pressure (you may feel dizzy or faint)

If any of these become serious, or you notice any side effects not listed in this leaflet, please tell your doctor.

5. How to store Primalan

Keep out of the reach and sight of children.

Do not use Primalan after the expiry date which is stated on the blister and box (after Exp). The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original container in order to protect from light.

In order to respect the environment, if you stop using these tablets, return any tablets remaining in the pack to your pharmacist who will arrange for their destruction.

6. Further information

What Primalan 5 mg Tablets contains

The active substance is mequitazine.

The other ingredients are Lactose, Maize starch, Colloidal silicon dioxide (E551), Magnesium stearate and Microcrystalline cellulose (E460).

Each tablet contains 5 mg of mequitazine.

What Primalan looks like and contents of the pack

Primalan is a round white or almost white tablet, 9 mm in diameter, with a flat faced bevel-edge with two score-lines on one face. The score-lines can be used to divide the tablet into equal halves which is useful if your doctor has given you specific dose instructions.

Primalan 5 mg Tablets are available in tablet containers, in bottles containing 100 tablets, or in blister packs containing 6, 56, 60 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Pierre Fabre Médicament
45, Place Abel Gance
92100 Boulogne
France.

Manufacturer:

Pierre Fabre Médicament Production
Etablissement Progipharm
Rue du Lycée
45500 GIEN, France.

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

Pierre Fabre Ltd.

Tel: 01962 874400

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000

Please be ready to give the following information:

Product Name	Reference Number
Primalan 5 mg Tablets:	PL 05630/0028

This is a service provided by the Royal National Institute of the Blind.

This leaflet was last approved in {MM/YYYY}.

LABELLING

Labelling

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

1. NAME OF THE MEDICINAL PRODUCT

Primalan @ 5 mg Tablets
Mequitazine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 5 mg of Mequitazine

3. LIST OF EXCIPIENTS

Also includes lactose: see leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

100 tablets
60 tablets
56 tablets
6 tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use only.

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

Keep out of the reach and sight of children.
Read the leaflet carefully before use

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Store in the original container to protect from light

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

PIERRE FABRE MEDICAMENT
45, place Abel Gance
92100 Boulogne
France

12. MARKETING AUTHORISATION NUMBER(S)

PL 05630/0028

13. MANUFACTURER'S BATCH NUMBER

LOT {number}

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

Use as directed by your doctor

PICTOGRAM TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING**16. INFORMATION IN BRAILLE**

primalan 5 mg tablets

**MINIMUM PARTICULAR TO APPEAR ON SMALL IMMEDIATE
PACKAGING UNITS**

Blister

1. NAME OF THE MEDICINAL PRODUCT

Primalan ® 5 mg Tablets
Mequitazine

2. METHOD OF ADMINISTRATION

not applicable

3. EXPIRY DATE

EXP < mm.yyyy >

4. BATCH NUMBER

LOT

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

not applicable

6. OTHER

PIERRE FABRE MEDICAMENT

PARTICULARS TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING**1. NAME OF THE MEDICINAL PRODUCT**

Primalan ® 5 mg Tablets
Mequitazine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 5 mg of Mequitazine

3. LIST OF EXCIPIENTS

Also includes lactose: see leaflet for further information

4. PHARMACEUTICAL FORM AND CONTENTS

100 tablets

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use only.

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

Keep out of the reach and sight of children.
Read the leaflet carefully before use

7. OTHER SPECIAL WARNING(S), IF NECESSARY**8. EXPIRY DATE**

EXP {MM/YYYY}

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Store in the original container to protect from light

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

PIERRE FABRE MEDICAMENT
45, place Abel Gance
92100 Boulogne
France

12. MARKETING AUTHORISATION NUMBER(S)

PL 05630/0028

13. MANUFACTURER'S BATCH NUMBER

LOT {number}

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

Use as directed by your doctor

PICTOGRAM TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING**16. INFORMATION IN BRAILLE**

primalan 5 mg tablets