Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Ephedrine Hydrochloride 30mg in 1ml Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1ml ampoule contains 30mg of ephedrine hydrochloride.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for Injection
A clear colourless sterile solution for injection

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

To reduce hypotension during spinal anaesthesia.

4.2 Posology and method of administration

For single patient use only:

Adults and the elderly
Up to 30 mg in increments of 3 - 7.5 mg.
After the development of hypotension, by slow intravenous administration.

Children
0.5 - 0.75 mg / kg body weight or 17 - 25 mg / m^2 body surface.
After the development of hypotension, by slow intravenous administration.

4.3 Contraindications

Patients receiving treatment with monoamine oxidase inhibitors (or within 2 weeks of their withdrawal). Coronary thrombosis, diabetes mellitus, ischaemic heart disease, hypertension, thyrotoxicosis, closed angle glaucoma or, in the case of elderly patients prostatic hypertrophy.

4.4 Special warnings and precautions for use

Cardiovacular effects may be seen with sympathomimetic drugs including Ephedrine Hydrochloride 30 mg in 1 ml Solution for Injection. There is some evidence from post-marketing data and published literature of rare occurrences of myocardial ischaemia associated with beta agonists. Patients with underlying severe heart disease (e.g. ischaemic heart disease, arrhythmia or severe heart failure) who are receiving Ephedrine Hydrochloride 30 mg in 1 ml Solution for Injection should be warned to seek medical advice if they experience chest pain or other symptoms of worsening heart disease. Attention should be paid to assessment of symptoms such as dyspnoea and chest pain, as they may be of either respiratory or cardiac origin.

4.5 Interaction with other medicinal products and other forms of interactions

Patients receiving treatment with monoamine oxidase inhibitors (or within 2 weeks of their withdrawal). See also section 4.3.Contraindications.

4.6 Fertility, pregnancy and lactation

There is no, or inadequate evidence of safety of the drug in human pregnancy, but it has been in use for many years without apparent ill consequence. If drug therapy during pregnancy is needed the use of this drug is acceptable.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

The following side effects have been reported:

Giddiness, headache, nausea, vomiting, sweating, thirst, arrhythmias, tachycardia, precordial pain, palpitations, difficulty in micturition, muscular weakness, tremors, anxiety, restlessness and insomnia. In the case of patients with prostatic hypertrophy the retention of urine may become acute. Rarely allergic sensitisation has been reported.

Unknown: myocardial ischaemia* (see section 4.4)

* reported spontaneously in post-marketing data therefore frequency regarded as unknown.

4.9 Overdose

Symptoms
Giddiness, headache, nausea, vomiting, sweating, thirst, arrhythmias, tachycardia, precordial pain, palpitations, difficulty in micturition, muscular weakness, tremors, anxiety, restlessness and insomnia, paranoid psychosis, delusions and hallucinations may occur.

Treatment
In severe overdosage diazepam may be required to control CNS stimulation and severe hypertension will require specific therapy.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ephedrine is a sympathomimetic agent with direct and indirect effects on adrenergic receptors. It has alpha and beta-adrenergic activity and has pronounced stimulating effects on the central nervous system. It causes bronchodilation, relaxes the bladder wall, contracts the sphincter muscles, but relaxes the detrusor muscles.

It has stimulant action on the respiratory centre.

5.2 Pharmacokinetic properties

Ephedrine accumulates in the liver, lungs, kidneys, spleen and brain. It is largely excreted unchanged in the urine together with small amounts of metabolites.

It has a plasma half-life reportedly between 3 and 6 hours depending on the urinary pH; elimination is enhanced and half-life accordingly shorter in acid urine.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections.

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

Unopened: 3 years
Product should be used immediately after opening and any remaining contents discarded

6.4 Special precautions for storage

Do not store above 25°C.
Keep container in the outer carton to protect from light.

6.5 Nature and contents of container

1 ml clear colourless type I glass ampoules packed in cardboard cartons.
Pack size: 10 x 1 ml ampoules.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

For single use only. Discard any remaining contents immediately after use.

7 MARKETING AUTHORISATION HOLDER

Ethypharm
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92213 Saint-Cloud Cedex
France

8 MARKETING AUTHORISATION NUMBER

PA0549/027/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26 November 2004
Date of next Renewal: 26 November 2009

10 DATE OF REVISION OF THE TEXT

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