

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Hedex 500 mg Film-coated Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains paracetamol 500 mg.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film-coated tablet

White film coated capsule-shaped tablet with flat edges and a break line on one side. The break line is only to facilitate breaking for ease of swallowing and do not divide into equal doses.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

Hedex is a mild analgesic and antipyretic. The tablets are recommended for use in the short term management of headaches, including migraine and tension headaches, backache, rheumatic and muscle pain, period pains, nerve pains, toothache and for relieving of fever, aches and pains of colds and flu.

### 4.2 Posology and method of administration

Oral administration only.

#### Adults (including the elderly):

2 tablets repeated if necessary 3-4 times a day to a maximum of 8 tablets in any 24 hour period.

#### Paediatric population

#### Children 6-12 years:

The usual dose is 1 tablet repeated if necessary 3-4 times a day to maximum of 4 tablets in any 24 hour period. Hedex tablets are not suitable for children under 6 years of age.

These doses should not be repeated more frequently than every 4 hours and not more than 4 doses should be given in any 24 hour period.

Maximum duration of continued use without medical advice: 3 days.

### 4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1. Use in children under 6 years of age.

### 4.4 Special warnings and precautions for use

Hepatic impairment

Underlying liver disease increases the risk of paracetamol-related liver damage. Patients with renal or hepatic impairment should seek medical advice prior to treatment with paracetamol. The hazard of overdose is greater in those with non-cirrhotic alcoholic liver disease.

Do not exceed the stated dose.

Patients should be advised not to take other paracetamol-containing products concurrently. If symptoms persist, consult your doctor.

Keep out of the sight and reach of children.

Consult your doctor if you are taking warfarin or have been diagnosed with liver or kidney disease.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone. The rate of paracetamol absorption may be reduced by colestyramine. Colestyramine should not be administered within one hour of taking paracetamol.

The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

In case of concomitant treatment with probenecid, the dose of paracetamol should be reduced because the probenecid reduces the clearance of paracetamol by 50% because it prevents the conjugation of paracetamol with glucuronic acid.

There is limited evidence to suggesting that paracetamol may affect cholaramphenicol pharmacokinetics but its validity has been criticised and evidence of a clinically relevant interaction appears to lack. Although no routine monitoring needed, it is important to bear in mind this potential interaction when these two medications are concomitantly administered, especially in malnourished patients.

#### **4.6 Fertility, pregnancy and lactation**

##### Pregnancy

Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use.

##### Breast-feeding

Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breast feeding.

##### Fertility

There are no available data on the effect of paracetamol on fertility.

#### **4.7 Effects on ability to drive and use machines**

Hedex has no or negligible influence on the ability to drive and use machines.

#### **4.8 Undesirable effects**

Adverse events associated with paracetamol from historical clinical trial data are both infrequent and from small patient exposure. Accordingly, events reported from extensive post-marketing experience at therapeutic/labeled dose and considered attributable are tabulated below by System Organ Class and frequency. Frequencies are defined as: very common ( $>1/10$ ), common ( $>1/100$ ,  $<1/10$ ), uncommon ( $>1/1000$ ,  $<1/100$ ), rare ( $>1/10,000$ ,  $<1/1000$ ) and very rare ( $<1/10,000$ ), not known (cannot be estimated from the available data).

Immune system disorders	Allergies (not including angioedema)	Rare
Skin and subcutaneous tissue disorders	Cutaneous hypersensitivity reactions, including skin rashes, pruritus, sweating, purpura, urticaria and angioedema.	Very rare
	Toxic epidermal necrolysis (TEN), drug-induced dermatitis, Stevens Johnson syndrome. Anaphylaxis.	Very rare
Haematological system disorders	Thrombocytopaenia	Very rare
Respiratory system disorders	Aggravation of bronchospasm has been reported in asthmatic patients known to be sensitive to aspirin and other non-steroidal anti-inflammatory drugs	Very rare
Hepatobiliary disorders	Liver dysfunction	Very rare
Renal and urinary disorders	Sterile pyuria (cloudy urine)	Very rare

**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 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).

**4.9 Overdose**

Symptoms of paracetamol overdose in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In sever poisoning, hepatic failure may progress to encephalopathy, coma and death. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported. Liver damage is possible in adults who have taken 10g or more of paracetamol. It is considered that excess quantities of a toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested), become irreversibly bound to liver tissue.

Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention and any patient who has ingested around 7.5g or more of paracetamol in the preceding 4 hours should undergo gastric lavage. Administration of oral methionine or intravenous N-acetylcysteine which may have a beneficial effect up to at least 48 hours after the overdose, may be required. General supportive measures must be available.

Risk factors:

If the patient

- a) is on long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St. John’s Wort or other drugs that induce liver enzymes
- or
- b) regularly consumes ethanol in excess of recommended amounts
- or
- c) is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia

**5 PHARMACOLOGICAL PROPERTIES**

**5.1 Pharmacodynamic properties**

ATC Code: N02BE01

Paracetamol is an analgesic and antipyretic. Its mechanism of action is believed to include inhibition of prostaglandin synthesis, primarily within the central nervous system.

## 5.2 Pharmacokinetic properties

Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract.

Concentration in plasma reaches a peak in 30-60 minutes.

Plasma half-life is 1-4 hours.

Paracetamol is relatively uniformly distributed throughout most body fluids.

Plasma protein binding is variable.

Excretion is almost exclusively renal, in the form of conjugated metabolites.

## 5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

- Maize starch
- Potassium sorbate
- Talc
- Stearic acid
- Povidone
- Pre-gelatinised starch
- Hypromellose
- Triacetin

## 6.2 Incompatibilities

Not applicable.

## 6.3 Shelf life

4 years.

## 6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

## 6.5 Nature and contents of container

Opaque PVC/aluminium foil blister strips packed into cardboard boxes containing 12, 16, 24 or 40 tablets.

Not all pack sizes may be marketed.

## 6.6 Special precautions for disposal

No special requirements.

**7 MARKETING AUTHORISATION HOLDER**

Chefaro Ireland Limited  
Treasury Building  
Lower Grand Canal Street  
Dublin 2  
Ireland

**8 MARKETING AUTHORISATION NUMBER**

PA1186/009/001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 20 August 1992

Date of last renewal: 20 August 2007

**10 DATE OF REVISION OF THE TEXT**

August 2017