SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

PARALEN EXTRA TO RELIEVE PAIN
film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains paracetamol 500 mg and caffeine 65 mg.
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet
Product description: off-white to yellowish biconvex film-coated tablets, with "PARALEN EXTRA" embossed on one side.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Paralen Extra to relieve pain is an analgesic and antipyretic agent which acts rapidly against severe and moderately severe pain. Tablets are recommended for the majority of painful and feverish conditions such as headaches including migraine, toothache, neuralgia of various origin, sore throat, menstrual pains, rheumatic aches, backache, muscle and joint pain during influenza and common cold. Simultaneously, it reduces fever.

4.2. Posology and method of administration

The product is designed for oral use.

Adults (including elderly) and adolescents
1 - 2 tablets according to needs up to 4 times daily with a time interval of 4 hours as minimum. The single dose of 1 tablet is appropriate for individuals weighing less than 60 kg while the single dose of 2 tablets is appropriate only for individuals weighing 60 kg and more. The maximum single dose is 1 g of paracetamol (2 tablets), the maximum daily dose is 4 g of paracetamol (8 tablets). With long-term treatment (more than 10 days), the daily dose should not exceed 2.5 g of paracetamol.

Children aged 12-15 years
One film-coated tablet up to 3 times a day given 6 hours apart as minimum. The product is not suitable for children younger than 12 years.

Patients with renal insufficiency

Dose adjustment is necessary: 500 mg can be given every 6 hours at the glomerular filtration rate 50-10 mL/min; in values less than 10 mL/min the medicine is given every 8 hours.

4.3. Contraindications

The product is contraindicated:

- in known hypersensitivity to paracetamol, caffeine or to any of the excipients listed in section 6.1,
- in severe renal and hepatic insufficiency, acute hepatitis,
- in concomitant administration of drugs affecting liver function,
- in glucoso-6-phosphatehydrogenase enzyme deficiency,
- in haemolytic anaemia,
- in alcoholism.

4.4. Specials warnings and precautions for use

Regular monitoring of liver function tests is recommended in patients with impaired hepatic function and those receiving high doses of paracetamol over a long period.

Measurement of prothrombine time is required in concomitant therapy with oral anticoagulants and high doses of paracetamol.

Intake of alcohol has to be avoided during the therapy.

Patients should be warned not to use simultaneously other paracetamol-containing products.

Consumption of excessive amounts of coffee or tea during the treatment may induce the feeling of stress and irritation.

When at high doses (above 6 g daily), paracetamol is toxic for the liver. However, a hepatic affection may develop also at much lower doses if alcohol, hepatic inductors or other agents toxic for the liver are coactive (see section 4.5). The long-term consumption of alcohol increases significantly a risk of paracetamol hepatotoxicity, with the highest risk being recorded in chronic alcoholics who are subject to abstinence for a short time (12 h).

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

The absorption rate of paracetamol may be enhanced by metoclopramide or domperidone, while cholestyramine may lead to its reduction.

Co-administration of agents that postpone evacuation of stomach contents, such as propantheline, may delay the absorption of paracetamol and its onset of action.

The anticoagulation effect of warfarin or other coumarin products may be elevated together an increased risk of bleeding due to regular daily use of paracetamol. Occasional use has not significant effect.

Hepatotoxic substances may elevate potential accumulation and overdose with paracetamol.

Paracetamol enhances the plasmatic level of acetylsalicylic acid and chloramphenicol.

Probenecid and salicylamide affect elimination and concentration of paracetamol in plasma.

When used concomitantly with medicaments inducing hepatic enzymes, e.g. certain hypnotics and antiepileptic agents (apart from others glutethimide, phenobarbital, phenytoin, carbamazepine), and with rifampicin, doses of paracetamol, which are safe otherwise, may cause hepatic disorders. The same applies to alcohol abuse.

On concomitant administration of paracetamol with lamotrigine reduction of lamotrigine efficacy has been reported under elevation of its hepatic clearance.

Concomitant use of paracetamol and isoniazid may result in an increased risk of hepatotoxicity.

Enhanced aptitude to the development of neutropenia and hepatotoxicity has been reported on concomitant use of paracetamol and zidovudine. Therefore, this medicine should be used concomitantly with zidovudine only after careful evaluation of benefit/risk ratio of treatment.

Concurrent use of clozapine and caffeine may result in an increased risk of clozapine toxicity.

4.6. Fertility, pregnancy and lactation

Pregnancy
Epidemiological studies carried out during pregnancy have not demonstrated detrimental effects of paracetamol and coffeine used at recommended doses. It is not advisable to use the product during the first trimester of pregnancy. The administration during the second and the third trimester of pregnancy must be considered by the physician.

Breastfeeding
Paracetamol passes into milk of nursing mothers but its amounts are not clinically significant. Paracetamol and its metabolites have not been demonstrated in urine of the breast-fed infant. No adverse reactions have been reported in breastfed infants even during long-term experience with paracetamol use except for one single case of maculopapular rash.
On short-term treatment and concomitant cautious monitoring of the baby, it is not necessary to discontinue breast-feeding.

4.7. Effects on ability to drive and use machines.

No influence on the ability to drive and use machines.

4.8. Undesirable effects

The incidence of adverse drug reactions to paracetamol at therapeutic doses is only rare.
The following table summarises adverse drug reactions divided into groups according to MedDRA terminology together with their frequency: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to < 1/1,000); very rare (<1/10,000):

MedDRA system organ class	**Frequency**	**Undesirable effect**

Blood and lymphatic system disrders	very rare	agranulocytosis, hemolytic anemia, leukopenia, neutropenia, pancytopenia, thrombocytopenia
Hepatobiliary disorders	very rare	jaundice
Respiratory, thoracic and mediastinal disorders	very rare	bronchospasm
Skin and subcutaneous tissue disorders	rare	allergic skin reactions, rash

Caffeine can cause the following adverse drug reactions (divided into groups according to MedDRA terminology):

MedDRA system organ class	**Frequency**	**Undesirable effect**
Psychiatric disorders	common	restlessness, insomnia due to stimulation of the central nervous system
Gastrointestinal disorders	common	nausea caused by irritation of the gastrointestinal tract

4.9. Overdose

Signs

Overdose with even relatively low paracetamol doses (8 to 15 g in dependence on the body mass of the patient) may result in a severe damage of the liver and, sometimes, acute renal tubular necrosis. Paleness, nausea, vomiting, inappetence and abdominal pains rank among symptoms of paracetamol overdose during the first 24 hours. Symptoms of a hepatic damage may develop within 12-24 hours after the ingestion. Abnormalities of the glucose metabolism and metabolic acidosis may develop. In severe intoxication, the hepatic failure may result in encephalopathy, coma and death. An acute renal failure with acute tubular necrosis has been reported, although a severe hepatic affection was missing. Also cardiac arrhythmia and pancreatitis have been recorded. Affections of the liver in adult individuals may develop after ingestion of a dose of 10 g of paracetamol or a higher one. An excessive amount of the toxic metabolite (usually adequately detoxified by glutathion after the ingestion of normal doses of paracetamol) is irreversibly bound to the hepatic tissue.
Prolongation of the prothrombin time is one of indicators of an impaired function of the liver, and therefore its monitoring is suitable. Higher inclination to hepatic affections is recorded in patients treated with enzyme inducers (carbamazepine, phenytoin, barbiturates, rifampicin) or patients with the abuse of alcohol.

Treatment

Immediate treatment is necessary to manage the overdose by paracetamol. Although significant early symptoms are missing, the patient should be transferred to hospital to get under medical surveillance. Gastric lavage should be carried out in the patient who has ingested a dose of about 7.5 g or higher during recent 4 hours. Thereafter, methionine should be administered (2.5 g orally) or a specific antidote N-acetylcysteine intravenously (over 8-15 hours after the intoxication), which have a favorable effect as late as within 48 hours after overdose. Acetylcysteine is usually administered to adult patients and children i.v. in 5% glucose, the initial dose should be 150 mg/kg of body mass in the course of 15 minutes. Furthermore, 50 mg/kg in an infusion of 5% glucose for a period of 4 hours, and then 100

mg/kg within hour 16 resp. 20 after the commencement of treatment. Acetylcysteine may be administered also per os within 10 hours after the ingestion of a toxic dose of paracetamol sized 70-140 mg/kg 3x daily. Measures and procedures to ensure basic vital functions must be available. Hemodialysis or hemoperfusion is in place at very severe intoxication.
High doses of caffeine may induce headaches, tremor, nervousness and irritation.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: paracetamol, combinations excl. psycholeptics
ATC code: N02BE51

Paracetamol is an analgesic – antipyretic agent without anti-inflammatory action and with a good gastrointestinal tolerance. It may be used in adult patients as well as in children.
The mechanism of action is probably similar to the activity of acetylsalicylic acid and depends on inhibition of prostaglandins in the central nervous system. This inhibition is however selective.
Blood sugar is not affected and thus it may be used in diabetic patients. Blood clotting is not affected, it has no influence on uric acid level and its elimination in urine. Paracetamol may be administered in all cases where salicylates are contraindicated.
The analgesic effect of paracetamol after a single administration of a dose of 0.5-1 g persists for 3-6 hours, its antipyretic effect lasts for 3-4 hours. The two effects are comparable with acetylsalicylic acid at identical doses.
Caffeine enhances the analgesic effect of paracetamol by stimulating the central nervous system, and thus depression - that is often associated with pain - may be alleviated.

5.2. Pharmacokinetic properties

Paracetamol absorption from the gastrointestinal tract is fast and almost complete. The maximum plasmatic level is being achieved within 15 to 60 minutes after administration and the half-life in plasma is 1-4 hours after therapeutic doses. In case of a severe hepatic insufficiency, it is prolonged up to 5 hours. At renal insufficiency, the half-life is not protracted but as the renal elimination is limited, the dose of paracetamol must be reduced.
Paracetamol is relatively evenly distributed into the majority of body fluids. The bond to plasmatic proteins varies; 20-30 % may be bound in concentrations captured at acute intoxication. The excretion is practically exclusively renal in the form of conjugated metabolites. About 5 % of paracetamol is eliminated in their unchanged form.
Paracetamol crosses the placental barrier, passing into milk of nursing mothers.

5.3 Preclinical safety data

No experimental data are available which would facilitate a reliable assessment whether mutagenic, carcinogenic, teratogenic and embryo-toxic potential of the fix-combination is different from risks of individual constituents alone.

a) Acute toxicity
It is known that in man the oral use of more than 6 g of paracetamol may lead to signs of acute intoxication. At plasmatic concentrations of 200 – 300 μg/ml over 4 hours, 100 – 150

µg/ml over 8 hours, 50 – 80 µg/ml over 12 hours, and 30 – 45 µg/ml over 15 hours, damage of hepatocytes with lethal termination in hepatic coma has been reported. The hepatotoxicity of paracetamol is directly proportional to its plasmatic concentrations. Drugs inducing hepatic enzymes and alcohol may call for a hepatic affection even at paracetamol doses which are otherwise non-toxic.

b) Chronic toxicity
In animal experiments studying sub-chronic and chronic toxicity of paracetamol in rats and mice, damage in the gastrointestinal tract, alterations in blood picture, degeneration of the hepatic and renal parenchyma up to necrosis have been reported. These alterations have been caused by paracetamol mode of action on the one hand, and on the other hand – owing to its metabolism. Metabolites to which toxic effects are being attributed and related organ alterations have been demonstrated in humans, too. Therefore, paracetamol should not be used on a long-term basis and at higher doses. Cases of reversible chronic active hepatitis have been described with doses as low as 3.9 and 2.9 g and on use for a period of one year.

An evident affection of the liver may occur on long-term use of higher oral doses (about 6 g of paracetamol) for a period of e.g. three weeks also in the liver which has not been damaged prior to use of the agent, e.g. in persons not consuming alcohol.

c) Mutagenic and carcinogenic potential
Comprehensive studies have revealed no signs of a more significant genotoxic risk of paracetamol administered at doses corresponding to the therapeutic, i.e. non-toxic dose.

Long-term studies in rats and mice have provided no findings of relevant carcinogenic effects at non-hepatotoxic dosage of paracetamol.

d) Reproduction toxicity
Animal experiments and hitherto human experience have indicated no activity of paracetamol as regards damage of the fetus.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Core:
Pregelatinized maize starch
Povidone 30
Croscarmellose sodium
Stearic acid
Microcristalline cellulose

Coating:
Hypromellose 2910/5
Macrogol 6000
Titanium dioxide
Simeticone emulsion SE 4
Talc

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

2 years

6.4. Special precautions for storage

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

6.5. Nature and contents of container

Blister (Al/colorless, transparent PVC), folding box
Size of package: 12 and 24 tablets
Not all pack sizes may be marketed.

6.6. Special precautions for disposal

No special requirements.

7. MARKETING AUTHORIZATION HOLDER

Zentiva, k.s., Prague, Czech Republic

8. MARKETING AUTHORIZATION NUMBER(S)

[To be completed nationally]

9. DATE OF FIRST AUTHORIZATION/RENEVAL OF THE AUTHORIZATION

[To be completed nationally]

10. DATE OF REVISION OF THE TEXT

[To be completed nationally]

PARTICULARS TO APPEAR ON THE FOLDER

1. NAME OF THE MEDICINAL PRODUCT

PARALEN EXTRA TO RELEIVE PAIN
(paracetamolum/coffeinum)

2 STATEMENT OF ACTIVE SUBSTANCE(S)

Paracetamolum 500 mg, Coffeinum 65 mg in each film-coated tablet

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

12 film-coated tablets
24 film-coated 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

Using of doses higher than recommended can lead to a risk of severe damage of the liver function. If you suffer from liver disease, have problems with consuming alcohol, or if you use any other paracetamol-based drugs, administration is possible only if recommended by a doctor.

8. EXPIRY DATE

Exp:

9. SPECIAL STORAGE CONDITIONS

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

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

Return unused drugs into the pharmacy.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zentiva, k.s.
U Kabelovny 130 Dolní Měcholupy
102 37 Prague 10
Czech Republic

12. MARKETING AUTHORISATION NUMBER(S)

Reg.No:

13. BATCH NUMBER

Batch No.:

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product not subject to medical prescription.

15. INSTRUCTIONS ON USE

Adults: 1-2 tablets 4-times daily at least 4 hours apart. Use at most 2 tablets at once and at most 8 tablets during 24 hours. The single dose of 2 tablets is appropriate only for individuals weighing 60 kg and more.
Children aged 12-15: 1 tablet at most 3-times daily and at least 6 hours apart. Use always only 1 tablet and at most 3 tablets during 24 hours.
Do not administer to children younger than 12 years.

16. INFORMATION IN BRAILLE

PARALEN EXTRA TO RELEIVE PAIN

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

1. NAME OF THE MEDICINAL PRODUCT

PARALEN EXTRA TO RELEIVE PAIN
(paracetamolum/coffeinum)

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Logo ZENTIVA

3. EXPIRY DATE

Exp:

4. BATCH NUMBER

Batch No:

5. OTHER

Package leaflet: information for the user

PARALEN EXTRA TO RELIEVE PAIN

(paracetamolum/coffeinum)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet:
1. What PARALEN EXTRA TO RELIEVE PAIN is and what it is used for
2. What you need to know before you use PARALEN EXTRA TO RELIEVE PAIN
3. How to use PARALEN EXTRA TO RELIEVE PAIN
4. Possible side effects
5. How to store PARALEN EXTRA TO RELIEVE PAIN
6. Contents of the pack and other information

1. What PARALEN EXTRA TO RELIEVE PAIN is and what is it used for

PARALEN EXTRA TO RELIEVE PAIN contains a combination of two active substances, which is efficient against pain. Paracetamol ensures relief of pain and reduces body temperature. Caffeine intensifies the effect of paracetamol and thus it helps to relieve pain, it acts against tiredness, it slightly supports breathing and blood circulation at feverish diseases. PARALEN EXTRA TO RELIEVE PAIN does not irritate the stomach. It does not contain acetylsalicylic acid.
The product may be used by the adults, adolescents and children older than 12 years.
PARALEN EXTRA TO RELIEVE PAIN is suitable for alleviation of headaches, migraine, backaches, toothaches, rheumatic and muscular pains and menstrual pains. It also brings relief of unpleasant symptoms of flu, cold and sore throat and reduces fever.

2. What you need to know before you take PARALEN EXTRA TO RELIEVE PAIN

Do not use PARALEN EXTRA TO RELIEVE PAIN
- if you are allergic to paracetamol, caffeine (active ingredients of the product) or to any other ingredients of this medicine (listed in section 6),
- at jaundice, acute liver inflammation, chronic alcohol intake,
- if you suffer from severe liver or renal disease,
- if you use concomitantly other drugs damaging liver
- if you suffer from haemolytic anaemia (lack of blood cells) or glucose-6-phosphate-dehydrogenase enzyme deficiency (an hereditary condition leading to low red blood cell counts).

If you are not sure if you should start taking PARALEN EXTRA TO RELIEVE PAIN, ask your physician.

Warnings and precautions
Talk to your doctor or pharmacist before taking PARALEN EXTRA TO RELIEVE PAIN if you are treated for some disease of the liver or kidney.
While taking PARALEN EXTRA TO RELIEVE PAIN you should not take any other medicines which contain paracetamol.
Liver damage is possible in adults who have taken 6 g or more of paracetamol a day.
However, a hepatic affection may develop also at much lower doses if the patient has the following risk factors.

Risk factors:
If the patient
1.) is on long term treatment with carbamazepine, phenobarbital, phenytoin, rifampicin, or other drugs that induce liver enzymes (see section Other medicines and PARALEN EXTRA TO RELIEVE PAIN)
or
2.) regularly consumes alcohol in excess of recommended amounts. The long-term consumption of alcohol increases significantly a risk of paracetamol hepatotoxicity, with the highest risk being recorded in chronic alcoholics who are subject to abstinence for a short time (12 h).

Other medicines and PARALEN EXTRA TO RELIEVE PAIN
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.
While taking PARALEN EXTRA TO RELIEVE PAIN you should not take any other medicines which contain paracetamol.
The effect of PARALEN EXTRA TO RELIEVE PAIN and the effects of metoclopramide, domperidone, propantheline, cholestyramine, clozapine, salicylamide and probenecid may influence each other.
Long-term concomitant use with some drugs against epilepsy (phenobarbitale, phenytoin, carbamazepin, lamotrigin), glutethimide (used to treat insomnia), zidovudine (used in HIV infections and AIDS), isoniazid (antibiotic) and rifampicine (antibiotic) may result in damage of liver function in some cases.
The risk of bleeding may be increased due to regular daily use of PARALEN EXTRA TO RELIEVE PAIN together with some anticoagulants (warfarine).
It is not suitable to combine PARALEN EXTRA TO RELIEVE PAIN with products containing acetylsalicylic acid by reason of the higher risk of kidney damage.

If you use any of the above mentioned medicines please consult your doctor or pharmacist before taking PARALEN EXTRA TO RELIEVE PAIN.

In the course of use of the product, restrict intake of products containing caffeine (medicaments, coffee, tea, cola) because higher doses of caffeine may induce nervousness, insomnia and – exceptionally – also acceleration of the activity of the heart.

PARALEN EXTRA TO RELIEVE PAIN with food, drink and alcohol
The product can be used irrespective of meal. In the course of use of the product, you must not drink alcohol beverages and you should restrict intake of drinks containing caffeine (coffee, tea, cola).

Pregnancy and breast-feeding
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.
It is not advisable to use PARALEN EXTRA TO RELIEVE PAIN during the first trimester of pregnancy. The administration during the rest of pregnancy must be considered by the physician.
On short-term treatment with PARALEN EXTRA TO RELIEVE PAIN, it is not necessary to discontinue breast-feeding, but the baby must be monitored cautiously.

Driving and using machines
Alertness remains unaffected.

3. How to use PARALEN EXTRA to relieve pain

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

Adults and adolescents: 1 - 2 tablets as necessary, up to four times daily at time intervals at least 4 hours. The single dose of 1 tablet is appropriate for individuals weighing less than 60 kg while the single dose of 2 tablets is appropriate only for individuals weighing 60 kg and more.
The highest individual dose is 2 tablets. Do not use more than 8 tablets during 24 hours.

Children aged 12-15: 1 tablet at most three times daily at an interval of at least 6 hours. The highest individual dose is 1 tablet. Do not administer more than 3 tablets within 24 hours.
Do not administer the product in children younger than 12 years.

Do not exceed the recommended dosage. Tablets should be followed with a sufficient amount of liquid.
Do not use the product without physician´s recommendation for more than 7 days. If your symptoms do not improve within 3 days, ask your doctor for advice.

If you take more PARALEN EXTRA TO RELIEVE PAIN than you should
Ingestion of 6g or more of paracetamol may lead to liver damage.
Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. In severe poisoning, hepatic failure may progress to encephalopathy (impairment of brain function), haemorrhage, low blood sugar, cerebral oedema, and death. Acute renal failure, strongly suggested by loin pain, blood and protein in the urine, may develop even in the absence of severe liver damage. Irregular heartbeat and pancreatitis (an inflammation of the pankreas presents with severe stomach pain and vomiting) have been reported.
High doses of caffeine may induce headaches, tremor, nervousness and irritation.

Seek immediate medical advice in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage. Bring any remaining tablets with you to show the doctor.

If you forget to take PARALEN EXTRA TO RELIEVE PAIN
If needed, take the omitted dose of the product as soon as you mention it. Do not take the next dose after less than 4 hours.
Do not take a double dose to make up for forgotten dose.

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

4. Possible side effects

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

If sudden, unexpected reactions as urticaria or breathing difficulties arise, discontinue the administration of the product and seek for a doctor immediately.

During the administration of paracetamol or caffeine (the active substances of PARALEN EXTRA TO RELIEVE PAIN), the following side effects may occur (ranged according to their occurrence):
Common (possible occurence in 1 - 10 patients out of 100):
- restlessness, insomnia, nausea

Rare (possible occurence in in 1 - 10 patients out of 10 000):
- allergic skin reactions, rash

Very rare (possible occurence in less than 1 patient out of 10 000):
- narrowing of the bronchi, jaundice, blood cells formation disturbances.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

5. How to store PARALEN EXTRA to relieve pain

Keep this medicine out of the sight and reach of children.
Store in the original package in order to protect from light.
Do not use this medicine after the expiry date which is stated on the package. 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. These measures will help protect the environment.

6. Contents of the pack and other information

What PARALEN EXTRA TO RELIEVE PAIN contains
The active substances are: paracetamol 500 mg and caffeine 65 mg in each film-coated tablet.

The other ingredients are: pre-gelatinized maize starch, povidone 30, crosscarmellose sodium, stearic acid, microcrystalline cellulose, hypromellose 2910/5, macrogol 6000, titanium dioxide, simethicone emulsion SE 4, talc.

What PARALEN EXTRA TO RELIEVE PAIN looks like and contents of the pack
PARALEN EXTRA TO RELIEVE PAIN are off-white to yellowish round biconvex film-coated tablets, with "PARALEN EXTRA" embossed on one side.

Pack size: 12 or 24 film-coated tablets.
Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer
[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under following names:

Czech Republic	PARALEN EXTRA PROTI BOLESTI
Slovak Republic	Paralen Extra

This leaflet was last revised in