SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Asda Max Strength Sinus Relief Capsules, Hard
Boots Max Strength Sinus Pressure & Pain Relief Capsules, hard
Superdrug Max Strength Sinus Relief Capsules, Hard
Wilko Max Strength Sinus Relief Capsules, Hard
Sudafed Blocked Nose & Sinus Capsules
Numark Max Strength Sinus Relief Capsules, Hard
Morrisons Max Strength Sinus Relief Capsules
Sudafed Sinus Max Strength Capsules, Hard
Sudafed Congestion & Headache Relief Max Strength Capsules, Hard

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient	**mg/Capsule**
Paracetamol	500
Caffeine	25
Phenylephrine Hydrochloride	6.1

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Capsule, hard (capsule)

Red/blue hard gelatin capsules containing the drug product, an off-white powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of symptoms associated with the pain and congestion of sinusitis, including relief of aches and pains, headache, nasal congestion and lowering of temperature.

4.2 Posology and method of administration

Route of administration: Oral
Swallow whole with water. Do not chew.

For all indications:
Adults, the elderly and children aged 16 years and over:
Two capsules every 4 to 6 hours when necessary to a maximum of 8 capsules (4 doses) in 24 hours.

Dosage should not be continued for longer than 3 days without consulting a doctor.

Children under 16 years:
Not to be used unless recommended by a doctor.

4.3 Contraindications

Paracetamol: Hypersensitivity to paracetamol or any of the other constituents.

Caffeine: Should be given with care to patients with a history of peptic ulcer.

Phenylephrine Hydrochloride: Severe coronary heart disease and cardiovascular disorders. Hypertension. Hyperthyroidism. Contraindicated in patients currently receiving or within two weeks of stopping therapy with monoamine oxidase inhibitors.

Not to be used in children under the age of 16 years.

Avoid in patients with prostatic enlargement.

4.4 Special warnings and precautions for use

Care is advised in the administration of paracetamol to patients with severe renal or severe hepatic impairment. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.

Use with caution in patients with Raynaud's Phenomenon and diabetes mellitus.

The following warnings will appear on the pack: -

CONTAINS PARACETAMOL
Do not take anything else containing paracetamol while taking this medicine.
Talk to a doctor at once if you take too much of this medicine, even if you feel well. Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor. Keep out of the sight and reach of children.

The Label shall say:

Talk to a doctor at once if you take much of this medicine, even if you feel well.

The Leaflet shall say:

Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage. Go to your nearest hospital casualty department. Take your medicine and this leaflet with you.

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.

This medicine contains less than 1 mmol sodium (23 mg) per 2 capsules, that is to say essentially 'sodium-free'.

Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or in patients with malnutrition or other sources of glutathione deficiency (e.g. chronic alcoholism) who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring, is recommended. The measurement of urinary 5-oxoproline may be useful to identify pyroglutamic acidosis as underlying cause of HAGMA in patients with multiple risk factors.

4.5 Interaction with other medicinal products and other forms of interaction

Enzyme-inducing drugs may increase hepatic damage, as does excessive intake of alcohol. The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by cholestyramine. These interactions are considered to be of unlikely clinical significance in acute usage at the dosage regimen proposed.
Medical advice should be sought before taking paracetamol-caffeine-phenylephrine in combination with the following drugs:

Monoamine oxidase inhibitors (including moclobemide)	Hypertensive interactions occur between sympathomimetic amines such as phenylephrine and monoamine Oxidase inhibitors (see contraindications).

Sympathomimetic amines	Concomitant use of phenylephrine with other sympathomimetics amines can increase the risk of cardiovascular side effects (see warnings and precautions).
Beta-blockers and other antihypertensives (including debrisoquine, guanethidine, reserpine, methyldopa)	Phenylephrine may reduce the efficacy of betablocking drugs and antihypertensive drugs. The risk of hypertension and other cardiovascular side effects may be increased (see contraindications).
Tricyclic antidepressants (eg amitriptyline)	May increase the risk of cardiovascular side effects with phenylephrine (see contraindications)
Digoxin and cardiac glycosides	Concomitant use of phenylephrine with digoxin or cardiac glycosides may increase the risk of irregular heartbeat or heart attack
Ergot alkaloids	(ergotamine and methysergide) increased risk of ergotism
Warfarin and other coumarins	The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with an increased risk of bleeding; occasional doses have no significant effect.

Paracetamol

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by colestyramine.

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

Drugs which induce hepatic microsomal enzymes, such as alcohol, barbiturates, monoamine oxidase inhibitors and tricyclic antidepressants, may increase the hepatotoxicity of paracetamol, particularly after overdosage. Contraindicated in patients currently receiving or within two weeks of

stopping therapy with monoamine oxidase inhibitors because of a risk of hypertensive crisis.

Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis due to pyroglutamic acidosis , especially in patients with risk factors (see section 4.4)

Phenylephrine Hydrochloride

Phenylephrine may adversely interact with other sympathomimetics, vasodilators and beta blockers.

4.6 Fertility, pregnancy and lactation

Paracetamol

A large amount of data on pregnant women indicate neither malformative, nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

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

Caffeine

Taken during pregnancy, it appears that the half-life of caffeine is prolonged. This is a possible contributing factor in hyperemesis gravidarum (morning sickness).

Caffeine appears in breast milk. Irritability and poor sleeping pattern in the infant have been reported.

Phenylephrine Hydrochloride

Due to the vasoconstrictive properties of phenylephrine the product should be used with caution in patients with a history of pre-eclampsia. Phenylephrine may reduce placental perfusion and the product should be used in pregnancy only if the benefits outweigh this risk. There is no information on use in lactation.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

The frequency of occurrence of undesirable effect is usually classified as follows: *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)
Not known (incidence cannot be assessed on the basis of the available data).

Adverse events of paracetamol from historical clinical trial data are both infrequent and from small patient exposure. Accordingly, events reported from extensive post-marketing experience at therapeutic/labelled dose and considered attributable are tabulated below by system class. Due to limited clinical trial data, the frequency of these adverse events is not known (cannot be estimated from available data), but post-marketing experience indicates that adverse reactions to paracetamol are rare and serious reactions are very rare.

Paracetamol

Body System	**Undesirable effect**
Blood and lymphatic system disorders	Thrombocytopenia Agranulocytosis These are not necessarily causally related to paracetamol.
Immune system disorders	Anaphylaxis Cutaneous hypersensitivity reactions including skin rashes, angiodema and Stevens Johnson syndrome, toxic epidermal necrolysis
Respiratory, thoracic and mediastinal disorders	Bromchospasm*
Hepatobiliary disorders	Hepatic dysfunction
Metabolism and nutrition disorders	High anion gap metabolic acidosis (Frequency Unknown)

* There have been cases of bronchospasm with paracetamol, but these are more likely in asthmatics sensitive to aspirin or other NSAIDs.

Description of selected adverse reactions
High anion gap metabolic acidosis
Cases of high anion gap metabolic acidosis due to pyroglutamic acidosis have been observed in patients with risk factors using paracetamol (see section 4.4).
Pyroglutamic acidosis may occur as a consequence of low glutathione levels in these patients.

Caffeine
Adverse reactions identified through post-marketing use with caffeine are listed below. The frequency of these reactions is unknown.

Central Nervous system	Nervousness and anxiety Irritability, Restlessness and Excitability Dizziness

When the recommended paracetamol-caffeine dosing regimen is combined with dietary caffeine intake, the resulting higher dose of caffeine may increase the potential for caffeine-related adverse effects such as insomnia, restlessness, anxiety, irritability, headaches, gastrointestinal disturbances and palpitations.

Phenylephrine
The following adverse events have been observed in clinical trials with phenylephrine and may therefore represent the most commonly occurring adverse events.

Body System	**Undesirable effect**
Psychiatric disorders	Nervousness
Nervous system disorders	Headache, dizziness, insomnia
Cardiac disorders	Increased blood pressure
Gastrointestinal disorders	Nausea, vomiting, diarrhoea

Adverse reactions identified during post-marketing use are listed below. The frequency of these reactions is unknown.

Eye disorders	Mydriasis, acute angle closure glaucoma, most likely to occur in those with closed angle glaucoma
Cardiac disorders	Tachycardia, palpitations
Skin and subcutaneous disorders	Allergic reactions (e.g. rash, urticaria, allergic dermatitis). Hypersensitivity reactions – including cross-sensitivity with other sympathomimetics may occur
Renal and urinary disorders	Dysuria, urinary retention. This is most likely to occur in those with bladder outlet obstruction, such as prostatic hypertrophy.

Very rare cases of serious skin reactions have been reported.

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

PARACETAMOL

Liver damage is possible in adults who have taken 10g or more of paracetamol. Ingestion of 5g or more of paracetamol may lead to liver damage if the patient has risk factors (see below).

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.

Symptoms

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. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia, cerebral oedema, and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

Management

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. Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be in accordance with established treatment guidelines, see British National Formulary (BNF) overdose section.

Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable). Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of paracetamol, however, the maximum protective effect is obtained up to 8 hours post-ingestion. The effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous N-acetylcysteine, in line with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24 hours from ingestion should be discussed with the National Poisons Information Service (NPIS) or a liver unit.

CAFFEINE

Doses over 1g are probably necessary to induce toxicity, 2 – 5g to produce severe toxicity and 5 – 10g is likely to be lethal.

Symptoms include: epigastric pain, vomiting, diuresis, tachycardia, CNS stimulation (insomnia, restlessness, excitement, agitation, jitteriness, tremors, convulsions).

No specific antidote is available, reduce or stop dosage and avoid excessive intake of coffee or tea.

PHENYLEPHRINE HYDROCHLORIDE

Severe overdosage may produce hypertension and associated reflex bradycardia. Treatment measures include early gastric lavage and symptomatic and supportive measures. The hypertensive effects may be treated with an alpha-receptor blocking agent (such as phentolamine mesylate 6 – 10 mg) given intravenously, and the bradycardia treated with atropine, preferably only after the pressure has been controlled.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic Group: Other analgesics and antipyretics &
Other cold combination preparations

ATC code: N02BE51

PARACETAMOL

Analgesic:

The mechanism of analgesic action has not been fully determined. Paracetamol may act predominantly by inhibiting a prostaglandin synthesis in the central nervous system (CNS) and to a lesser extent through a peripheral action by blocking pain-impulse generation. The peripheral action may also be due to inhibition of prostaglandin synthesis or to inhibition of the synthesis or actions of other substances that sensitise pain receptors to mechanical or chemical stimulation.

Antipyretic:

Paracetamol probably produces antipyresis by acting on the hypothalamic heat-regulating centre to produce peripheral vasodilation resulting in increased blood flow through the skin, sweating and heat loss. The central action probably involves inhibition of prostaglandin synthesis in the hypothalamus.

CAFFEINE

Central nervous system stimulant – Caffeine stimulates all levels of the CNS, although its cortical effects are milder and of shorter duration than those of amfetamines.

Analgesia Adjunct:

Caffeine constricts cerebral vasculature with an accompanying decrease in cerebral blood flow and in the oxygen tension of the brain. It is believed that caffeine helps to relieve headache by providing a more rapid onset of action and/or enhanced pain relief with lower doses of analgesic. Recent studies with ergotamine indicate that the enhancement of effect by the addition of caffeine may also be due to improved gastrointestinal absorption of ergotamine when administered with caffeine.

PHENYLEPHRINE HYDROCHLORIDE

Sympathomimetic amines, such as phenylephrine, act on alpha-adrenergic receptors of the respiratory tract to produce vasoconstriction, which temporarily reduces the

swelling associated with inflammation of the mucous membranes lining the nasal and sinus passages. This allows the free drainage of the sinusoidal fluid from the sinuses.

In addition to reducing mucosal lining swelling, decongestants also suppress the production of mucus, therefore preventing a build up of fluid within the cavities which could otherwise lead to pressure and pain.

5.2 Pharmacokinetic properties

PARACETAMOL

Absorption and Fate

Paracetamol is rapidly absorbed from the gastro-intestinal tract with peak plasma concentrations occurring between 10 and 120 minutes after oral administration. It is metabolised in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half-life varies from about 1 to 4 hours.

Plasma-protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations.

A minor hydroxylated metabolite which is usually produced in very small amounts by mixed-function oxidases in the liver and which is usually detoxified by conjugation with liver glutathione may accumulate following paracetamol overdose and cause liver damage.

CAFFEINE

Absorption and Fate

Caffeine is absorbed readily after oral administration and is widely distributed throughout the body. Caffeine is metabolised almost completely via oxidation, demethylation, and acetylation, and is excreted in the urine as 1-methyluric acid, 1-methylxanthine, 7-methylxanthine, 1,7-dimethylxanthine (paraxanthine), 5-acetylamino-6-formylamino-3-methyluracil (AFMU), and other metabolites with only about 1% unchanged.

PHENYLEPHRINE HYDROCHLORIDE

Absorption and Fate

Phenylephrine has reduced bioavailability from the gastro-intestinal tract owing to irregular absorption and first-pass metabolism by monoamine oxidase in the gut and liver.

5.3 Preclinical safety data

Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch

Croscarmellose Sodium

Sodium Laurilsulfate

Magnesium Stearate

Talc

Gelatin

Titanium Dioxide E171

Quinoline Yellow E104

Patent Blue V E131

Erythrosine E127

Indigo Carmine E132

6.2 Incompatibilities

None known.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Pack size 12 capsules.
Pack size 16 capsules.

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

Wrafton Laboratories Limited
Wrafton
Braunton
Devon
EX33 2DL

8 MARKETING AUTHORISATION NUMBER(S)

PL 12063/0067

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10/03/2011

10 DATE OF REVISION OF THE TEXT

25/04/2025