Hyoscine
N-butylbromide
Paracetamol

Buscopan VENUS

WHAT IS HYOSCINE-N-BUTYLBROMIDE+ PARACETAMOL (BUSCOPAN VENUS)?

Hyoscine-N-butylbromide + Paracetamol (Buscopan Venus) is an antispasmodic-analgesic combination used for the relief from the pain of stronger abdominal cramps including menstrual cramps and urinary tract spasm.

WHAT IS CONTAINED IN HYOSCINE-N-BUTYLBROMIDE + PARACETAMOL (BUSCOPAN VENUS)?

1 film-coated tablet contains

Hyoscine-N-butylbromide ..... 10 mg

Paracetamol ..... 500 mg

Excipients: microcrystalline cellulose, sodium carboxymethylcellulose, dried maize starch, ethylcellulose, colloidal silica, hypromellose and magnesium stearate

HOW DOES HYOSCINE-N-BUTYLBROMIDE + PARACETAMOL (BUSCOPAN VENUS) WORK?

The active ingredients in Buscopan Venus are Hyoscine-N-butylbromide, a known antispasmodic substance that relieves the pain by acting on the muscle spasm which causes the pain; and Paracetamol which has analgesic properties. This special combination of Hyoscine-N-butylbromide + Paracetamol (Buscopan Venus) allows cramped muscles to relax and simultaneously delivers fast relief from pain.

HOW SHOULD I TAKE HYOSCINE-N-BUTYLBROMIDE + PARACETAMOL (BUSCOPAN VENUS)?

Hyoscine-N-butylbromide + Paracetamol (Buscopan Venus) should not be taken over prolonged period of time (for more than 3 days) without a prescription from the physician.

The following doses are recommended:

Adults: 1-2 tablets, 3 times daily.

The total daily dose should not exceed 6 tablets.

The tablets should not be chewed, but swallowed in whole with a sufficient amount of water.

Pediatric population

Children from 10 years onward may use Hyoscine-N-butylbromide + Paracetamol (Buscopan Venus) film-coated tablets, if required.

The film-coated tablets are not suitable for children under 10 years of age.

WHO CANNOT TAKE HYOSCINE-N-BUTYLBROMIDE + PARACETAMOL (BUSCOPAN VENUS)?

Hysocine-N-Butylbromide (Buscopan Venus) is contraindicated in

- known hypersensitivity to hyoscine butylbromide, or paracetamol or other components of the drug
- myasthenia gravis
- mechanical stenosis in the gastrointestinal tract
- paralytical or obstructive ileus
- megacolon
- severe hepatocellular insufficiency (Child-Pugh C)

In case of rare hereditary conditions that may be incompatible with an excipient of the product, the use of the product is contraindicated.

WHAT SHOULD I REMEMBER WHEN TAKING HYOSCINE-N-BUTYLBROMIDE+ PARACETAMOL (BUSCOPAN VENUS)?

In case severe, unexplained abdominal pain persists or worsens, or occurs together with symptoms like fever, nausea, vomiting, changes in bowel movements, abdominal tenderness, decreased blood pressure, fainting or blood in stool, medical advice should immediately be sought.

To prevent overdosing, it should be ensured that any other drugs taken concurrently do not contain paracetamol, one of the active components of Hyoscine-N-butylbromide + Paracetamol (Buscopan Venus). Liver damage may result if the recommended dosage for paracetamol is exceeded. Hyoscine-N-butylbromide + Paracetamol (Buscopan Venus) should be used with caution in:

- glucose-6- phosphate-dehydrogenase deficiency,
- chronic alcohol use including recent cessation of alcohol intake,
- Severe renal insufficiency,
- Gilbert's syndrome,
- Mild to moderate hepatocellular insufficiency (Child-Pugh A/8)
- Low glutathione reserves.

In such cases Hyoscine-N-butylbromide + Paracetamol (Buscopan Venus) should only be used under medical supervision and, if necessary, the dose reduced or the intervals between the individual administrations prolonged. The blood count and renal and liver function should be monitored after prolonged use.

Extensive use of analgesics, especially at high doses, may induce headaches that must not be treated with increased doses of the drug.

Severe acute hypersensitivity reactions (e.g. anaphylactic shock) are very infrequently observed. Treatment must be discontinued at the first signs of a hypersensitivity reaction following the administration of Hyoscine-N-butylbromide + Paracetamol (Buscopan Venus).

Severe cutaneous adverse reactions (SCARs):
Life-threatening cutaneous reactions Stevens-Johnson syndrome (SJS), and Toxic epidermal necrolysis (TEN) have been reported with the use of Hyoscine-N-butylbromide + Paracetamol (Buscopan Plus). Patients should be advised of the signs and symptoms and monitored closely for skin reactions. If symptoms or signs of SJS and TEN (e.g. progressive skin rash often with blisters or mucosal lesions) occur, patients should immediately stop Hyoscine-N-butylbromide + Paracetamol (Buscopan Plus) treatment and seek medical advice.

Caution is advised in patients with underlying sensitivity to aspirin and/or to non-steroidal anti-inflammatory drugs (NSAIDs)

Hepatotoxicity may occur with paracetamol even at therapeutic doses, after short treatment duration and in patients without pre-existing liver dysfunction.

Abrupt discontinuation of analgesic after prolonged use at high doses may induce withdrawal symptoms (e.g. headache, tiredness, nervousness), that typically resolve within few days.

Reintake of analgesics should depend upon physician's advice, and withdrawal symptoms abated.

Hyoscine-N-butylbromide + Paracetamol (Buscopan Venus) should not be taken for more than 3 days unless directed by a physician. The patient should be instructed to seek medical advice, if pain persists or gets worse, if new symptoms occur, or if redness or swelling is present because these could be signs of a serious condition.

Because of the potential risk of anticholinergic complications, caution should be used in patients prone to narrow angle glaucoma as well as in patients susceptible to intestinal or urinary outlet obstructions and in those inclined to tachyarrhythmia.

Hyoscine-N-butylbromide + Paracetamol (Buscopan Venus) tablets contain 4.32 mg of sodium per unit resulting in 25.92 mg sodium per maximum recommended daily dose. To be taken into consideration for patients on a controlled sodium diet.

CAN I TAKE OTHER DRUGS TOGETHER WITH HYOSCINE-N-BUTYLBROMIDE + PARACETAMOL (BUSCOPAN VENUS)?

Yes, but not with the following: certain hypnotics and anti-epileptics (e.g. glutethimide, phenobarbital, phenytoin, carbamazepine) as well as rifampicin. The same applies to potentially hepatotoxic substances and alcohol abuse.

Paracetamol may increase the risk of bleeding in patients taking warfarin and other antivitamin K. Patients taking paracetamol and antivitamin K should be monitored for appropriate coagulation and bleeding complications.

Co-administration of flucloxacillin with paracetamol may lead to metabolic acidosis, particularly in patients presenting risk factors of glutathione depletion, such as sepsis, malnutrition or chronic alcoholism.

Cholestyramine reduces the absorption of paracetamol.

The anticholinergic effect of drugs such as tri- and tetracyclic antidepressants, antihistamines, antipsychotics, quinidine, amantadine, disopyramide and other anticholinergics (e.g. tiotropium, ipratropium, atropine-like compounds) may be intensified by Hyoscine-N-butylbromide + Paracetamol (Buscopan Venus).

Concomitant treatment with dopamine antagonists such as metoclopramide may result in diminution of the effects of both drugs on the gastrointestinal tract.

The tachycardic effects of beta-adrenergic agents may be enhanced by Hyoscine-N-butylbromide + Paracetamol (Buscopan Venus).

Acceleration of gastric emptying, e.g. after administration of metoclopramide or domperidone, leads to an increase in the absorption rate of paracetamol.

CAN PREGNANT AND LACTATING WOMEN TAKE HYOSCINE-N-BUTYLBROMIDE + PARACETAMOL (BUSCOPAN VENUS)?

There are no adequate data on use of Hyoscine-N-butylbromide + Paracetamol (Buscopan Venus) during pregnancy.

Long experience with the mono substances has shown insufficient evidence of adverse effects during human pregnancy.

During pregnancy, paracetamol should not be taken for prolonged periods, in high doses, or in combination with other medicinal products as the safety has not been confirmed in such cases. Therefore, Hyoscine-N-butylbromide + Paracetamol (Buscopan Venus) is not recommended during pregnancy.

For Hyoscine-N-butylbromide, safety during lactation has not yet been established. However, adverse effects on the newborn have not been reported.

Paracetamol enters breast milk, but is not likely to affect the infant when therapeutic doses are used.

No studies on the effects on human fertility have been conducted.

WHAT SIDE EFFECTS MAY HAPPEN WHEN I TAKE HYOSCINE-N-BUTYLBROMIDE + PARACETAMOL (BUSCOPAN VENUS)?

The following CIOMS frequency rating is used, when applicable: Very common $\geq$ 10%; Common $\geq$ 1 and $<$ 10%; Uncommon $\geq$ 0.1 and $<$ 1%; Rare $\geq$ 0.01 and $<$ 0.1%; Very rare $<$ 0.01%; Not known (cannot be estimated from available data).Blood and lymphatic system disorders

Not known: Agranulocytosis, thrombocytopenia, neutropenia, leukopenia, hemolytic anemia in particular

Immune system disorders

Uncommon: Skin reactions, sweating abnormal,

Rare: Blood pressure decreased including shock,

Not known: Anaphylactic reactions, dyspnoea, hypersensitivity such as anaphylactic shock, angioedema

Cardiac disorders

Rare: Tachycardia

Respiratory, thoracic and mediastinal disorders

Not known: Bronchospasm (especially in patients with a history of bronchial asthma or allergy)

Skin and subcutaneous disorders

Very rare: Erythema, urticaria, rash,

Not known: Toxic Epidermal Necrolysis (TEN), Stevens-Johnson syndrome (SJS), acute generalized exanthematous pustulosis, fixed drug eruption

Gastrointestinal disorders

Uncommon: Dry mouth

Hepatobiliary disorders

Not known: cytolytic hepatitis, which may lead to acute hepatic failure

Renal and urinary disorders

Not known: Urinary retention

WHAT MIGHT HAPPEN IF AN OVERDOSE OF HYOSCINE•N•BUTYLBROMIDE + PARACETAMOL (BUSCOPAN VENUS) IS TAKEN?

Signs and Symptoms

Hyoscine-N-butylbromide may include pallor, nausea, vomiting, anorexia and abdominal pain.

Paracetamol

Patients may then experience a temporary subjective improvement but mild abdominal pain possibly indicative of liver damage may persist.

Overdosage with paracetamol may cause hepatic cytolysis which can lead to hepatocellular insufficiency, gastrointestinal bleeding, metabolic acidosis, encephalopathy, disseminated intravascular coagulation, coma and death.

Increased levels of hepatic transaminases, lactate deshydrogenase and bilirubin with a reduction in prothrombin level can appear 12 to 48 hours after acute overdosage.

It can also lead to pancreatitis, acute renal failure and pancytopenia.

WHAT CAN BE DONE IF AN OVERDOSE OF HYOSCINE•N BUTYLBROMIDE + PARACETAMOL (BUSCOPAN VENUS) IS TAKEN?

Hyoscine-N-Butylbromide
If required, parasympathomimetic drugs should be administered. Opthalmological advice should be sought urgently in cases of glaucoma. Cardiovascular complications should be treated according to usual therapeutic principles.
In case of respiratory paralysis: intubation, artificial respiration should be considered. Catherisation may be required for urinary retention. In addition, appropriate supportive measures should be used as required.

Paracetamol
Where paracetamol intoxication is suspected, intravenous administration of SH group donators such as N-acetylcysteine within the first 10 hours after ingestion is indicated. Although N-acetylcysteine is most effective if initiated within this period, it can still offer some degree of protection if given as late as 48 hours after ingestion; in this case, it is taken for longer. The plasma concentration of paracetamol can be decreased by dialysis. Determinations of the plasma concentration of paracetamol are recommended.

Further measures will depend on the severity, nature and course of clinical symptoms of paracetamol intoxication and should follow standard intensive care protocols.

Interferences with laboratory and diagnostic test

Intake of paracetamol may impact the lab determination of uric acid by phosphotungstic acid and of blood glucose by glucose oxidase-peroxidase.

HOW IS HYOSCINE-N-BUTYLBROMIDE + PARACETAMOL (BUSCOPAN VENUS) AVAILABLE?

BUSCOPAN VENUS is available in:

Film-coated Tablets ..... Pack of 100's

Store at temperatures not exceeding 30°C

For suspected adverse drug reactions, report to **www.fda.gov.ph** and **CHCPV@sanofi.com**. Patients should seek medical attention immediately at the first sign of any adverse drug reaction.

By reporting side effects, you can help provide more information on the safety of this product

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Store in a safe place out of the reach of children!

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