SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nurofen Sinus & Blocked Nose 200mg/5mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients	Quantity
Ibuprofen	200.0mg
Phenylephrine hydrochloride	5.0mg

For full list of excipients, see Section 6.1

Excipients with known effect:
Sunset Yellow E 110.

3 PHARMACEUTICAL FORM

Yellow film coated tablet, printed with an identifying motif (IPE) in black ink

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of symptoms of cold and ‘flu with associated congestion, including aches and pains, headache, fever, sore throat, blocked nose and sinuses.

4.2 Posology and method of administration

For oral administration and short-term use only.
The lowest effective dose should be used for the shortest duration necessary to relieve symptoms (see section 4.4).
Adults, the elderly and children over 12 years:
The patient should consult a doctor if symptoms persist or worsen, or if the product is required for more than 10 days.

Two tablets up to 3 times a day. Leave at least four hours between doses and do not take more than 6 tablets in any 24hour period.

Not to be given to children under 12 years.

4.3 Contraindications

Hypersensitivity to ibuprofen, phenylephrine or any of the excipients in the product.
Hypertension and severe coronary heart disease.

Patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis, angioedema or urticaria) in response to aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs).

Active or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes or proven ulceration or bleeding).

History of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy.

Severe heart failure (NYHA Class IV), renal failure or hepatic failure (see Section 4.4).

Last trimester of pregnancy.

Use with concomitant NSAIDs including cyclo-oxygenase-2 specific inhibitors (see Section 4.5).

Hyperthyroidism.

Contraindicated in patients currently receiving or within two weeks of stopping therapy with monoamine oxidase inhibitors.

Avoid in patients with prostatic enlargement.

Phaeochromocytoma: Phenylephrine should not be used in patients with phaeochromocytoma.

4.4 Special warnings and precautions for use

Ibuprofen

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see gastrointestinal and cardiovascular risks below).

The elderly are at increased risk of consequence of adverse reactions to NSAIDs, especially gastrointestinal bleeding and perforation which may be fatal.

Respiratory: Bronchospasm may be precipitated in patients suffering from or with a previous history of bronchial asthma or allergic disease.

Other NSAIDs: The use of this product with concomitant NSAIDs, including cyclo-oxygenase-2 selective inhibitors, should be avoided (see section 4.5).

SLE and mixed connective tissue disease: Systemic lupus erythematosus and mixed connective tissue disease - increased risk of aseptic meningitis (see section 4.8).

Renal: Renal impairment as renal function may further deteriorate, especially in dehydrated children and adolescents (see sections 4.3 and 4.8).

Renal tubular acidosis and hypokalaemia may occur following acute overdose and in patients taking ibuprofen products over long periods at high doses (typically greater than 4 weeks), including doses exceeding the recommended daily dose.

Hepatic:
Hepatic dysfunction (see sections 4.3 and 4.8).

Cardiovascular and cerebrovascular effects:
Cases of Kounis syndrome have been reported in patients treated with Nurofen Sinus & Blocked Nose 200mg/5mg Tablets. Kounis syndrome has been defined as cardiovascular symptoms secondary to an allergic or hypersensitive reaction- associated with constriction of coronary arteries and potentially leading to myocardial infarction.

Caution (discussion with doctor or pharmacist) is required prior to starting treatment in patients with a history of hypertension and/or heart failure as fluid retention, hypertension and oedema have been reported in association with NSAID therapy.

Clinical studies suggest that use of ibuprofen, particularly at a high dose (2400 mg/day) may be associated with a small increased risk of arterial thrombotic events (for example, myocardial infarction or stroke). Overall, epidemiological studies do not suggest that low dose ibuprofen (≤1200 mg/day) is associated with an increased risk of arterial thrombotic events.

Patients with uncontrolled hypertension, congestive heart failure (NYHA II-III), established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease should only be treated with ibuprofen after careful consideration and high doses (2400 mg/day) should be avoided.

Careful consideration should also be exercised before initiating long-term treatment of patients with risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking), particularly if high doses of ibuprofen (2400 mg/day) are required.

Impaired female fertility: There is limited evidence that drugs which inhibit

cyclo-oxygenase/prostaglandin synthesis may cause impairment of female fertility by an effect on ovulation. This is reversible on withdrawal of treatment.

Gastrointestinal: NSAIDs should be given with care to patients with a history of gastrointestinal disease (ulcerative colitis, Crohn's disease) as these conditions may be exacerbated (see section 4.8).

GI bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at any time during treatment, with or without warning symptoms or a previous history of serious GI events.

The risk of GI bleeding, ulceration or perforation is higher with increasing NSAID doses, in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation (see section 4.3), and in the elderly. These patients should commence treatment on the lowest dose available.

Patients with a history of GI toxicity, particularly the elderly, should report any unusual abdominal symptoms (especially GI bleeding), particularly in the initial stages of treatment.

Caution should be advised in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as oral corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors or antiplatelets agents such as aspirin (see Section 4.5).

When GI bleeding or ulceration occurs in patients receiving ibuprofen, the treatment should be withdrawn.

Severe cutaneous adverse reactions (SCARs):
Severe cutaneous adverse reactions (SCARs), including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome (SJS), Toxic Epidermal Necrolysis (TEN), and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS syndrome), and acute generalized exanthematous pustulosis (AGEP), which can be life-threatening or fatal, have been reported in association with the use of ibuprofen (see section 4.8). Most of these reactions occurred within the first month.

If signs and symptoms suggestive of these reactions appear ibuprofen should be withdrawn immediately and an alternative treatment considered (as appropriate)

Masking of symptoms of underlying infections:

This medicinal product can mask symptoms of infection, which may lead to delayed initiation of appropriate treatment and thereby worsening the outcome of the infection. This has been observed in bacterial community acquired pneumonia and bacterial complications to varicella. When this medicine is administered for fever or pain relief in relation to infection, monitoring of

infection is advised. In non-hospital settings, the patient should consult a doctor if symptoms persist or worsen.

The label will include:

Read the enclosed leaflet before taking this product.

Do not take if you:

- Have (or have had two or more episodes of) a stomach ulcer, perforation or bleeding.
- Are allergic to ibuprofen or any other ingredient of the product, aspirin or other related painkillers.
- Are taking other NSAID painkillers, other products containing phenylephrine or aspirin with a daily dose above 75 mg.
- Are in the last 3 months of pregnancy

Speak to a pharmacist or your doctor before taking if you:

- Have or have had asthma, diabetes, high cholesterol, high blood pressure, a stroke, heart, liver, kidney or bowel problems.
- Are a smoker.
- Are pregnant.

If symptoms persist or worsen, consult your doctor.

Phenylephrine

Phenylephrine should be used with care in patients with cardiovascular disease, diabetes mellitus, closed angle glaucoma, Raynaud’s Phenomenon and hypertension.

The product contains an azo colouring agent Sunset Yellow E 110 which may cause allergic reactions.

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

4.5 Interaction with other medicinal products and other forms of interaction

Ibuprofen

Ibuprofen should not be used in combination with:

Aspirin (acetylsalicylic acid): Concomitant administration of ibuprofen and acetylsalicylic acid is not generally recommended because of the potential of

increased adverse effects, unless low-dose aspirin (not above 75 mg daily) has been advised by a doctor (see Section 4.4).

Experimental data suggest that ibuprofen may competitively inhibit the effect of low dose aspirin (acetylsalicylic acid) on platelet aggregation when they are dosed concomitantly. Although there are uncertainties regarding extrapolation of these data to the clinical situation, the possibility that regular, long-term use of ibuprofen may reduce the cardioprotective effect of low-dose acetylsalicylic acid cannot be excluded. No clinically relevant effect is considered to be likely for the occasional ibuprofen use (see section 5.1).

Other NSAIDs including cyclo-oxygenase-2 selective inhibitors: Avoid concomitant use of two or more NSAIDs as this may increase the risk of adverse reactions (see Section 4.4).

Ibuprofen should be used with caution in combination with:

Anti-coagulants: NSAIDs may enhance the effects of anticoagulants such as warfarin
(see Section 4.4).

Antihypertensives and diuretics: NSAIDs may diminish the effect of these drugs.
Diuretics can increase the risk of nephrotoxicity.

Corticosteroids: Increased risk of gastrointestinal ulceration or bleeding (see Section
4.4).

Anti-platelet agents and selective serotonin-reuptake inhibitors (SSRIs): Increased risk of gastrointestinal bleeding (see Section 4.4).

Cardiac glycosides: NSAIDs may exacerbate cardiac failure, reduce GFR and increase plasma glycoside levels.

Lithium: There is evidence for potential increase in plasma levels of lithium.

Methotrexate: There is potential for an increase in plasma methotrexate.

Ciclosporin: Increased risk of nephrotoxicity.

Mifepristone: NSAIDs should not be used for 8-12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone.

Tacrolimus: Possible increased risk of nephrotoxicity when NSAIDs are given with
tacrolimus.

Zidovudine: Increased risk of haematological toxicity when NSAIDs are given with

zidovudine. There is evidence of an increased risk of haemarthroses and haematoma in HIV(+) haemophiliacs receiving concurrent treatment with zidovudine and ibuprofen.

Quinolone antibiotics: Animal data indicate that NSAIDs can increase the risk of convulsions associated with quinolone antibiotics. Patients taking NSAIDs and quinolones may have an increased risk of developing convulsions.

Phenylephrine

Monoamine oxidase inhibitors (including moclobemide): hypertensive interactions occur between sympathomimetic amines such as phenylephrine and monoamine oxidase inhibitors (see section 4.3).

Sympathomimetic amines: concomitant use of phenylephrine with other sympathomimetic amines can increase the risk of cardiovascular side effects.

Beta-blockers and other antihypertensives (including debrisoquine, guanethidine, reserpine, methyldopa): phenylephrine may reduce the efficacy of beta-blockers and
antihypertensives. The risk of hypertension and other cardiovascular side effects may be increased (see section 4.3).

Tricyclic antidepressants (e.g. amitriptyline): may increase the risk of cardiovascular side effects with phenylephrine (see section 4.3).

Digoxin and cardiac glycosides: concomitant use of phenylephrine may increase the risk of irregular heartbeat or heart attack.

4.6 Fertility, pregnancy and lactation

Ibuprofen

Whilst no teratogenic effects have been demonstrated in animal experiments, the use of this product should, if possible, be avoided during the first six months of pregnancy.

From the 20th week of pregnancy onward, ibuprofen use may cause oligohydramnios resulting from foetal renal dysfunction. This may occur shortly after treatment initiation and is usually reversible upon discontinuation. In addition, there have been reports of ductus arteriosus constriction following treatment in the second trimester, most of which resolved after treatment cessation. Therefore, during the first and second trimester of pregnancy, Ibuprofen should not be given unless clearly necessary. If ibuprofen is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible. Antenatal monitoring for oligohydramnios and ductus arteriosus constriction should be considered after exposure to Ibuprofen for several days

from gestational week 20 onward. Ibuprofen should be discontinued if oligohydramnios or ductus arteriosus constriction are found.

During the third trimester, ibuprofen is contraindicated as there is a risk of premature constriction/closure of the fetal ductus arteriosus with possible persistent pulmonary hypertension. The onset of labour may be delayed and the duration increased with an increased bleeding tendency in both mother and child (see section 4.3).

In limited studies, ibuprofen appears in the breast milk in very low concentrations and is unlikely to affect the breast-fed infant adversely.

See section 4.4 regarding female fertility.

Phenylephrine

The safety of this medicine during pregnancy and lactation has not been established but in view of a possible association of foetal abnormalities with first trimester exposure to phenylephrine, the use of the product during pregnancy should be avoided. In addition, because phenylephrine may reduce placental perfusion, the product should not be used in patients with a history of preeclampsia. In view of the lack of data on the use of phenylephrine during lactation, this medicine should not be used during breast feeding.

4.7 Effects on ability to drive and use machines

No adverse effects known

4.8 Undesirable effects

The following list of adverse effects relates to those experienced with ibuprofen at OTC doses (maximum 1200 mg ibuprofen per day) and phenylephrine hydrochloride, in short-term use. In the treatment of chronic conditions, under long-term treatment, additional adverse events may occur.

Adverse events which have been associated with ibuprofen and phenylephrine hydrochloride are given below, tabulated by system organ class and frequency. Frequencies are defined as: Very common (≥1/10); Common (≥1/100 and <1/10); Uncommon (≥1/1000 and <1/100); Rare (≥1/10,000 and <1/1000); Very rare (< 1/10,000); Not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

System Organ Class	Frequency	Adverse Events
Blood and Lymphatic System Disorders	Very rare	Haematopoietic disorders[1]
Immune System Disorders	Uncommon	Hypersensitivity with urticaria and pruritus[2]
	Very rare	Severe hypersensitivity reactions, including facial, tongue and throat swelling, dyspnoea, tachycardia, and hypotension (anaphylaxis, angioedema or severe shock) [2]
Nervous System Disorders	Uncommon	Headache
	Very rare	Aseptic meningitis[3]
Cardiac Disorders	Not known Not Known	Cardiac failure, oedema[4], palpitations Kounis Syndrome
Vascular Disorders	Not known	Hypertension[4]
Respiratory, Thoracic and Mediastinal Disorders	Not known	Respiratory tract reactivity comprising exacerbation of asthma, bronchospasm or dyspnoea[2]
Gastrointestinal Disorders	Uncommon	Abdominal pain, nausea and dyspepsia[5]
	Rare	Diarrhoea, flatulence, constipation and vomiting
	Very rare	Peptic ulcer, gastrointestinal perforation or gastrointestinal haemorrhage, melaena, haematemesis[6]. Mouth ulceration, gastritis
	Not known	Exacerbation of colitis and Crohn's disease[7]
Hepatobiliary Disorders	Very rare	Liver disorder
Skin and Subcutaneous Tissue Disorders	Uncommon	Skin rash[2]
	Very rare	Severe cutaneous adverse reactions (SCARs) (including Erythema multiforme, exfoliative dermatitis,

System Organ Class	Frequency	Adverse Events
		Stevens-Johnson syndrome, and toxic epidermal necrolysis)
	Not known	Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome) Acute generalised exanthematous pustulosis (AGEP) Photosensitivity reactions
Metabolism and Nutrition Disorders	Not known Not known	Decreased Appetite Hypokalaemia*
Renal and Urinary Disorders	Very rare	Acute renal failure[8]
	Not known	Urinary retention
	Not known	Ureteric colic, dysuria
	Not known	Renal tubular acidosis*
Investigations	Very rare	Haemoglobin decreased

Description of Selected Adverse Reactions

[1] Examples include anaemia, leucopenia, thrombocytopenia, pancytopenia and agranulocytosis. First signs are fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, unexplained bleeding and bruising.

[2] Hypersensitivity reactions have been reported following treatment with ibuprofen and these may consist of: (a) Non-specific allergic reaction and anaphylaxis. (b) Respiratory tract reactivity, e.g. asthma, aggravated asthma, bronchospasm or dyspnoea. (c) Various skin reactions, e.g. pruritus, urticaria, angioedema and, more rarely, exfoliative and bullous dermatoses (including epidermal necrolysis and erythema multiforme).

[3] The pathogenic mechanism of drug-induced aseptic meningitis is not fully understood. However, the available data on NSAID-related aseptic meningitis points to a hypersensitivity reaction (due to a temporal relationship with drug intake, and disappearance of symptoms after drug discontinuation). Of note, single cases of symptoms of aseptic meningitis (such as stiff neck, headache,

nausea, vomiting, fever or disorientation) have been observed during treatment with Ibuprofen in patients with existing auto-immune disorders (such as systemic lupus erythematosus and mixed connective tissue disease).

[4]Clinical studies suggest that use of ibuprofen, particularly at a high dose (2400 mg/day) may be associated with a small increased risk of arterial thrombotic events (for example, myocardial infarction or stroke) (see Section 4.4).

[5] The most commonly-observed adverse events are gastrointestinal in nature.

[6] Sometimes fatal, particularly in the elderly.

[7] See section 4.4.

[8] Especially in long-term use, associated with increased serum urea and oedema. Also includes papillary necrosis.

*Renal tubular acidosis and hypokalaemia have been reported in the post-marketing setting typically following prolonged use of the ibuprofen component at higher than recommended doses.

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

Ibuprofen

In children, ingestion of more than 400 mg/kg may cause symptoms. In adults, the dose response rate effect is less clear cut. The half-life in overdose is 1.5-3 hours.

Symptoms

Patients who have ingested clinically important amounts of NSAIDs will develop no more than nausea, vomiting, epigastric pain, or more rarely diarrhoea.
Tinnitus, headache and gastrointestinal bleeding are also possible. In more serious poisoning, toxicity is seen in the central nervous system, manifesting as drowsiness, occasionally excitation and disorientation or coma.
Occasionally patients develop convulsions. In serious poisoning metabolic acidosis may occur and prothrombin time/INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal

failure and liver damage may occur. Exacerbation of asthma is possible in asthmatics.

In serious poisoning metabolic acidosis may occur and the prothrombin time/INR may be prolonged, probably due to interference with the actions of circulating clotting factors. Acute renal failure and liver damage may occur.

Prolonged use at higher than recommended doses may result in severe hypokalaemia and renal tubular acidosis. Symptoms may include reduced level of consciousness and generalised weakness (see section 4.4 and section 4.8).

Management

Management should be symptomatic and supportive and include the maintenance of a clear airway and monitoring of cardiac and vital signs until stable. Consider oral administration of activated charcoal if the patient presents within 1 hour of ingestion of a potentially toxic amount. If frequent or prolonged, convulsions should be treated with intravenous diazepam or lorazepam. Give bronchodilators for asthma.

Phenylephrine

Features of severe overdose of phenylephrine include haemodynamic changes and cardiovascular collapse with respiratory depression.

Treatment includes early gastric lavage and symptomatic and supportive measures. Hypertensive effects may be treated with an intravenous alpha-receptor blocking agent.

Phenylephrine overdose is likely to result in: nervousness, headache, dizziness, insomnia, increased blood pressure, nausea, vomiting, mydriasis, acute angle closure glaucoma (most likely to occur in those with closed angle glaucoma), tachycardia, palpitations, allergic reactions (e.g. rash, urticaria, allergic dermatitis), dysuria, urinary retention (most likely to occur in those with bladder outlet obstruction, such as prostatic hypertrophy).

Additional symptoms may include hypertension, and possibly reflex bradycardia.
In severe cases confusion, hallucinations, seizures and arrhythmias may occur. Treatment should be as clinically appropriate. Severe hypertension may need to be treated with alpha blocking medicinal products such as phentolamine.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

M01AE51 - Ibuprofen, combinations.

Ibuprofen

Ibuprofen is a propionic acid derivative NSAID that has demonstrated its efficacy by inhibition of prostaglandin synthesis. In humans ibuprofen reduces inflammatory pain, swellings and fever. Furthermore, ibuprofen reversibly inhibits platelet aggregation.

The therapeutic effect of ibuprofen in symptoms relating to the common cold and influenza has a duration of up to 8 hours.

Experimental data suggest that ibuprofen may competitively inhibit the effect of low dose aspirin (acetylsalicylic acid) on platelet aggregation when they are dosed concomitantly. Some pharmacodynamic studies show that when single doses of ibuprofen 400mg were taken within 8 hours before or within 30 minutes after immediate release aspirin (acetylsalicylic acid) (81 mg), a decreased effect of aspirin (acetylsalicylic acid) on the formation of thromboxane or platelet aggregation occurred. Although there are uncertainties regarding extrapolation of these data to the clinical situation, the possibility that regular, long-term use of ibuprofen may reduce the cardioprotective effect of low-dose acetylsalicylic acid cannot be excluded. No clinically relevant effect is considered to be likely for occasional ibuprofen use (see section 4.5).

Phenylephrine

Phenylephrine is a post-synaptic alpha-receptor agonist with low cardioselective betareceptor affinity and minimal central stimulant activity. It is a recognised decongestant and acts by vasoconstriction to reduce oedema and nasal swelling.

5.2 Pharmacokinetic properties

Ibuprofen

Ibuprofen is rapidly absorbed following administration and is rapidly distributed throughout the whole body. The excretion is rapid and complete via the kidneys.

Maximum plasma concentrations are reached 45 minutes after ingestion if taken on an empty stomach. When taken with food, peak levels are observed after 1-2 hours. These times may vary with different dosage forms.

The half-life of ibuprofen is about 2 hours.

In limited studies, ibuprofen appears in the breast milk in very low concentrations.

Phenylephrine

Phenylephrine is absorbed from the gastrointestinal tract, but has reduced bioavailability by the oral route due to first-pass metabolism.

It retains activity as a nasal decongestant when given orally, the drug distributing through the systemic circulation to the vascular bed of the nasal mucosa.

When taken by mouth as a nasal decongestant, phenylephrine is usually given at intervals of 4-6 hours.

Ibuprofen and Phenylephrine Combination

The ibuprofen component of this fixed combination (ibuprofen 200mg plus phenylephrine hydrochloride 5mg) is absorbed faster than standard ibuprofen 200mg tablets, with therapeutic levels being reached in 26.4 minutes (from the fixed combination) as opposed to 55.2 minutes (for standard ibuprofen).

5.3 Preclinical safety data

There are no findings of relevance to the prescriber other than those already mentioned elsewhere in the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Sodium starch glycolate Type A
Hypromellose
Magnesium stearate
Talc
Mastercote yellow FA 0156
Black printing ink (The ink contains the following residual materials after application: shellac (E904), iron oxide black (E172), propylene glycol (E1520)).

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store in a dry place
Store in the original package
Store below 25ºC
Keep out of reach and sight of children

6.5 Nature and contents of container

A strip pack consisting of a blister tray of white pigmented 250 μm PVC/40 gsm PVDC laminate heat-sealed to lacquered 20 μm aluminium foil containing 2, 4 or 8 tablets. One or two trays packed in a cardboard carton (i.e. 4, 6, 8, 10, 12, 14 or 16 tablets).

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements for disposal.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Healthcare (UK) Limited
Dansom Lane
Hull
HU8 7DS
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00063/0687

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

09/01/2025

10 DATE OF REVISION OF THE TEXT

06/02/2025