Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Apfen Plus 200mg / 12.8mg Film-Coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains ibuprofen 200mg and codeine phosphate hemihydrate 12.8 mg.

Each tablet also contains 150mg of lactose monohydrate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet.

White, film-coated, capsule-shaped tablets which are embossed on one side with "+".

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the symptomatic relief of acute moderate pain in such conditions as soft tissue injuries, including sprains, strains and musculo-tendonitis, backache, non-serious arthritic and rheumatic conditions rheumatic and muscular pain, migraine, dental pain, dysmenorrhoea, which is not considered to be relieved by other analgesics such as paracetamol or ibuprofen alone.

4.2 Posology and method of administration

For oral administration and short-term use only.

Adults (including the elderly) and children aged 12 years and over:
One or two tablets, to be taken with water, three times daily.
Apfen Plus should be used at the lowest effective dose for the shortest period of time. The dose should not be repeated more frequently than every six hours.
Not more than six tablets should be taken in any 24-hour period.
Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms (see section 4.4).
The duration of treatment should be limited to 3 days and if no effective pain relief is achieved the patients/carers should be advised to seek the views of a physician.

Children under 12 years of age:
Ibuprofen-codeine must not be given to children under 12 years of age because of the risk of opioid toxicity due to the variable and unpredictable metabolism of codeine to morphine (see sections 4.3 and 4.4).

Elderly: NSAIDs should be used with particular caution in elderly patients who are more prone to adverse events. The lowest dose compatible with adequate safe clinical control should be employed. See also section 4.4.

4.3 Contraindications

Hypersensitivity to ibuprofen or codeine, or to any of the excipients.

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 previous peptic ulcer.

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

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

Use with aspirin (acetylsalicylic acid) unless low-dose aspirin (not above 75 mg daily) has been advised by a doctor (see section 4.5 Interaction with other medicinal products and other forms of interaction).

Use with concomitant NSAIDs including cyclo-oxygenase-2 specific inhibitors (see section 4.5 Interaction with other medicinal products and other forms of interaction).

Severe hepatic failure, renal failure or severe heart failure (NYHA Class IV) (See section 4.4. Special warnings and precautions for use).

Last trimester of pregnancy (see section 4.6 Pregnancy and lactation).

Use of codeine containing products is contraindicated in mothers who are breastfeeding (see section 4.6).

Codeine is contraindicated in all paediatric patients (0-18 years of age) who undergo tonsillectomy and/or adenoidectomy for obstructive sleep apnoea syndrome due to an increased risk of developing serious and life-threatening adverse reactions (see section 4.4).

Codeine is contraindicated in those patients who are known to be CYP2D6 ultra-rapid metabolisers.

4.4 Special warnings and precautions for use

The use of Apfen Plus with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided.

Apfen Plus should be used with caution in those with hypotension, hypothyroidism, Systemic lupus erythematosus and mixed connective tissue disease - increased risk of aseptic meningitis (see section 4.8 Undesirable effects).

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.

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

The elderly have an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal (see Section 4.2).

Gastrointestinal bleeding (GI), ulceration and perforation: GI bleeding, ulceration or perforation, which can be fatal, has been reported with all NSAIDs at anytime 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 Contraindications), and in the elderly. These patients should commence treatment on the lowest dose available. Combination therapy with protective agents (e.g. misoprostol or proton pump inhibitors) should be considered for these patients, and also for patients requiring concomitant low dose aspirin, or other drugs likely to increase gastrointestinal risk (see section 4.5 Interaction with other medicinal products and other forms of interaction).

Patients with a history of GI toxicity, particularly when 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 antiplatelet agents such as aspirin (see section 4.5 Interaction with other medicinal products and other forms of interaction).

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

NSAIDs should be given with care to patients with a history of gastrointestinal disease (ulcerative colitis, Crohn's disease) as their condition may be exacerbated (see section 4.8 - Undesirable effects).

There is a risk of renal impairment in dehydrated adolescents.
Renal impairment as renal function may further deteriorate (See section 4.3 Contraindications and section 4.8 Undesirable effects).

Hepatic dysfunction (See section 4.3 Contraindications and section 4.8 Undesirable effects).

There is some 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.

Care should be observed in administering the product to any patients whose condition may be exacerbated by opioids, particularly the elderly, who are especially sensitive to their central and gastrointestinal effects, those on concurrent CNS depressant drugs, those with prostate hypertrophy and those with inflammatory or obstructive bowel disorders.

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

Patients with a history of cholecystectomy should consult a doctor before using this product as it may cause acute pancreatitis in some patients.

Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDs (see section 4.8 Undesirable effects). Patients appear to be at highest risk of these reactions early in the course of therapy, the onset of the reaction occurring in the majority of cases within the first month of treatment. Apfen Plus should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

Exceptionally, varicella can be at the origin of serious cutaneous and soft tissue complications. To date, the contributing role of NSAIDs in the worsening of these infections cannot be ruled out. Thus, it is advisable to avoid use of Apfen Plus in case of varicella.

Prolonged use of any type of pain-reliever for headaches can make them worse. If this situation is experienced or suspected, medical advice should be obtained and treatment should be discontinued. The diagnosis of 'Medication Overuse Headache' should be suspected in patients who have frequent or daily headaches despite (or because of) the regular use of headache medications.

Prolonged regular use, except under medical supervision, may lead to physical and psychological dependence (addiction) and result in withdrawal symptoms, such as restlessness and irritability once use of the medication is stopped.

Cardiovascular and cerebrovascular effects
Clinical studies suggest that the use of ibuprofen, particularly at high doses (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 (e.g., 1200 mg daily) 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 of ibuprofen (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.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose galactose malabsorption should not take this medicine.

Keep out of the sight and reach of children.

Do not take for more than three days unless told to do so by your doctor.

CYP2D6 metabolism

Codeine is metabolised by the liver enzyme CYP2D6 into morphine, its active metabolite. If a patient has a deficiency or is completely lacking this enzyme an adequate analgesic effect will not be obtained. Estimates indicate that up to 7% of the Caucasian population may have this deficiency. However, if the patient is an extensive or ultra-rapid metaboliser there is an increased risk of developing side effects of opioid toxicity even at commonly prescribed doses. These patients convert codeine into morphine rapidly resulting in higher than expected serum morphine levels.

General symptoms of opioid toxicity include confusion, somnolence, shallow breathing, small pupils, nausea, vomiting, constipation and lack of appetite. In severe cases this may include symptoms of circulatory and respiratory depression, which may be life-threatening and very rarely fatal. Estimates of prevalence of ultra-rapid metabolisers in different populations are summarised below:

Population	Prevalence %
African/Ethiopian	29
African American	3.4 to 6.5
Asian	1.2 to 2
Caucasian	3.6 to 6.5
Greek	6.0
Hungarian	1.9
Northern European	1 to 2

Post-operative use in children

There have been reports in the published literature that codeine given post-operatively in children after tonsillectomy and/or adenoidectomy for obstructive sleep apnoea, led to rare, but life-threatening adverse events including death (see also section 4.3). All children received doses of codeine that were within the appropriate dose range; however there was evidence that these children were either ultra-rapid or extensive metabolisers in their ability to metabolise codeine to morphine.

Children with compromised respiratory function

Codeine is not recommended for use in children in whom respiratory function might be compromised including neuromuscular disorders, severe cardiac or respiratory conditions, upper respiratory or lung infections, multiple trauma or extensive surgical procedures. These factors may worsen symptoms of morphine toxicity.

4.5 Interaction with other medicinal products and other forms of interaction

Apfen Plus contains ibuprofen and should not be used in combination with:

Aspirin: Unless low-dose aspirin (not above 75 mg daily) has been advised by a doctor, as this may increase the risk of adverse reactions (see section 4.3 Contraindications & 5.1 Pharmacodynamic Properties).

Acetylsalicylic acid
Concomitant administration of ibuprofen and acetylsalicylic acid is not generally recommended because of the potential of increased adverse effects.

Experimental data suggest that ibuprofen may competitively inhibit the effect of low dose acetylsalicylic acid on platelet aggregation when they are dosed concomitantly. Although there are uncertainties regarding extra 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 5.1).

Other NSAIDs: As these may increase the risk of adverse effects (see section 4.3 Contraindications).

Apfen Plus contains ibuprofen and should be used with caution in combination with:

Corticosteroids: increased risk of gastrointestinal ulceration or bleeding (see section 4.4. Special warnings and precautions for use).

Anti-coagulants: NSAIDs may enhance the effects of anti-coagulants, such as warfarin (see section 4.4. Special warnings and precautions for use).

Anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs): increased risk of gastrointestinal bleeding (see section 4.4. Special warnings and precautions for use).

Antihypertensives and diuretics: NSAIDs may diminish the effects of these drugs.

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

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

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

Opioid analgesics should be given with care to patients receiving monoamine oxidase inhibitors (MAOIs). Opioid analgesics may interact with MAOIs and result in serotonin syndrome. The effect of CNS depressants (including alcohol) may be potentiated by codeine; these interactions are unlikely to be significant at the dosage involved.

Codeine may antagonise the effects of metoclopramide and domperidone on gastrointestinal motility.

4.6 Fertility, pregnancy and lactation

Use in pregnancy

Apfen Plus has harmful pharmacological effects on pregnancy and/or the foetus/new-born child. Apfen Plus should not be used during pregnancy unless clearly necessary.

Whilst no teratogenic effects have been demonstrated in animal studies, ibuprofen should, if possible, be avoided during the first six months of pregnancy.

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

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

See section 4.4. (Special warnings and precautions for use) regarding female fertility.

Codeine-containing products must not be used in pregnant women unless prescribed by a doctor.

Lactation

Apfen Plus Tablets must not be used while breastfeeding.

At normal therapeutic doses codeine and its active metabolite may be present in breast milk at very low doses and is unlikely to adversely affect the breast fed infant. However, if the patient is an ultra-rapid metaboliser of CYP2D6, higher levels of the active metabolite, morphine, may be present in breast milk and on very rare occasions may result in symptoms of opioid toxicity in the infant, which may be fatal.

4.7 Effects on ability to drive and use machines

Patients should be advised not to drive or operate machinery if affected by drowsiness.

4.8 Undesirable effects

Ibuprofen:
Hypersensitivity reactions have been reported and these may consist of:

a) Non specific allergic reactions and anaphylaxis.
b) Respiratory tract reactivity, e.g., asthma, aggravated asthma, bronchospasm, dyspnoea.
c) Various skin reactions, e.g., Pruritus, urticaria, angioedema and more rarely erythema multiforme).

The following list of adverse effects relates to those experienced with ibuprofen at OTC doses, for short-term use. In treatment of chronic conditions, under long-term treatment, additional adverse effects may occur.

The following convention has been utilised for the classification of undesirable effects: 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 (cannot be estimated from the available data)

Body system	**Undesirable effect**	**Frequency**
Immune system disorders	Hypersensitivity reactions with urticaria and pruritus. Aseptic meningitis	Uncommon
	Severe hypersensitivity reactions. Symptoms could be: facial, tongue and laryngeal swelling, dyspnoea, tachycardia, hypotension (anaphylaxis, Angioedema or severe shock). Exacerbation of asthma and bronchospasm.	Very rare
Gastrointestinal disorders	Abdominal pain, nausea and dyspepsia. Exacerbation of ulcerative colitis and Crohn's	Uncommon

	disease (see section 4.4 Special warnings or precautions for use).	
	Diarrhoea, flatulence, constipation and vomiting.	Rare
	Peptic ulcer, perforation or gastrointestinal haemorrhage, sometimes fatal, particularly in the elderly.	Very rare
Nervous system disorders	Headache.	Uncommon
Renal and urinary disorders	Acute renal failure, papillary necrosis, especially in long-term use, associated with increased serum urea and oedema.	Very rare
Hepatobiliary disorders	Liver disorders.	Very rare
Blood and lymphatic system disorders	Haematopoietic disorders (anaemia, leucopenia, thrombocytopenia, pancytopenia, agranulocytosis). First signs are: fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, unexplained bleeding and bruising).	Very rare
Skin and subcutaneous tissue disorders	Various skin rashes.	Uncommon
Cardiovascular disorders	Oedema, hypertension and cardiac failure	Uncommon
	Bullous reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis.	Very rare

Gastrointestinal: The most commonly observed adverse events are gastrointestinal in nature. Peptic ulcers, perforation or GI bleeding, sometimes fatal, particularly in the elderly, may occur (see section 4.4. Special warnings and precautions for use). Nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, Melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease (see section 4.4 - Special warnings and precautions for use) have been reported following administration. Less frequently, gastritis has been observed.

Cardiovascular and cerebrovascular effects: Clinical studies suggest that use of ibuprofen (particularly at high doses 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). Oedema, hypertension and cardiac failure have been reported in association with NSAID treatment.

Immune system: In patients with existing auto-immune disorders (such as systemic lupus erythematosus, mixed connective tissue disease) during treatment with ibuprofen, single cases of symptoms of aseptic meningitis, such as stiff neck, headache, nausea, vomiting, fever or disorientation have been observed (see section 4.4 Special warnings or precautions for use).

Others:
Hearing disturbance, blurred vision.

Codeine:
Codeine may cause constipation, nausea, dizziness and drowsiness according to dosage and individual susceptibility.

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; E-mail: medsafety@hpra.ie.

4.9 Overdose

Overuse of this product (either by taking for more than three days and / or taking a higher than recommended dose) may lead to physical or psychological dependency, including withdrawal symptoms such as restlessness and irritability on abrupt discontinuation of treatment.

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

Most 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 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. Exacerbation of asthma is possible in asthmatics.

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 one 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.

Codeine overdose: The effects in overdosage will be potentiated by simultaneous ingestion of alcohol and psychotropic drugs.

Symptoms
Central nervous system depression, including respiratory depression, may develop but is unlikely to be severe unless other sedative agents have been co-ingested, including alcohol, or the overdose is very large. The pupils may be pin-point in size; nausea and vomiting are common. Hypotension and tachycardia are possible but unlikely.

Management
This should include general symptomatic and supportive measures including a clear airway and monitoring of vital signs until stable. Consider activated charcoal if an adult presents within one hour of ingestion of more than 350 mg or a child more than 5 mg/kg.

Give naloxone if coma or respiratory depression is present. Naloxone is a competitive antagonist and has a short half-life, so large and repeated doses may be required in a seriously poisoned patient. Observe for at least four hours after ingestion, or eight hours if a sustained release preparation has been taken.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: N02 AJ08 – Codeine combinations excluding psycholeptics.

Ibuprofen has analgesic, antipyretic and anti-inflammatory properties. 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.
Codeine phosphate hemihydrate is a centrally-acting opioid analgesic.

Experimental data suggests that ibuprofen may competitively inhibit the effect of low dose aspirin on platelet aggregation when they are dosed concomitantly. Some pharmacodynamic studies show that when a single dose of ibuprofen 400mg was taken within 8 h before or within 30min after immediate release aspirin dosing (81mg), a decreased effect of 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).

Codeine is a centrally acting weak analgesic. Codeine exerts its effect through μ opioid receptors, although codeine has low affinity for these receptors, and its analgesic effect is due to its conversion to morphine. Codeine, particularly in combination with other analgesics such as paracetamol, has been shown to be effective in acute nociceptive pain.

5.2 Pharmacokinetic properties

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 approximately 45 minutes after ingestion if taken on an empty stomach. When taken with food, peak levels are observed after one to two hours. These times vary with different dosage forms.

The half-life of ibuprofen is about two hours.

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

Codeine phosphate is well absorbed after oral administration and is widely distributed. Peak plasma concentrations occur between 30 minutes and two hours after ingestion. The plasma half-life varies between three and four hours. About 85% of an oral dose is excreted in the urine within 24 hours, 40 to 70% is free or conjugated codeine, 5 to15% is free or conjugated morphine, 10 to 20% is free or conjugated norcodeine, and trace amounts may be free or conjugated normorphine.

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.

Studies in rats and mice have revealed no abnormal development or embryolethal effects of codeine at doses of 10-20 mg/kg and 5-30 mg/kg respectively. Codeine showed no genotoxic activity in the Ames test, mouse and rat micronucleus assays, and only induced chromosome aberrations in Chinese Hamster Ovary (CHO) cells at concentrations that delayed the cell cycle. There was no evidence of carcinogenic activity of codeine in mice and rats fed up to 3,000 and 1,600 ppm codeine, respectively, for two years.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet cores:
Microcrystalline cellulose
Hydrogenated vegetable oil
Sodium starch glycolate
Colloidal anhydrous silica
Cellactose 80 (contains lactose monohydrate and cellulose powder)

Tablet coating:
Hypromellose
Macrogol 400

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

White, opaque polyvinyl chloride (250mm) / aluminium foil (20mm) blister packs containing 4, 6, 10, 12, 16, 20, 24, 30, 32, 48, 60, 96, 100 or 108 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

GlaxoSmithKline Consumer Healthcare (Ireland) Limited
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Citywest Business Campus
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Ireland

8 MARKETING AUTHORISATION NUMBER

PA0678/109/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 9th March 2012

10 DATE OF REVISION OF THE TEXT

August 2017