Non Steroidal Anti-Inflammatory Drug

Airtal® 100 mg Film-coated Tablet

Aceclofenac

FORMULATION:
Each Aceclofenac (Airtal®) Film-coated tablet contains:
Aceclofenac 100mg

Excipients: microcrystalline cellulose, croscarmellose sodium, glyceryl palmitostearate, povidone, hydroxypropyl methyl cellulose, polyoxyl 40 stearate and titanium dioxide.

White circular biconvex film-coated tablets.

INDICATION:
Aceclofenac (Airtal®) is indicated for the relief of pain and inflammation in osteoarthritis, rheumatoid arthritis and ankylosing spondylitis.

MECHANISM OF ACTION:
Aceclofenac (Airtal®) is a non-steriodal agent with anti-inflammatory and analgesic properties. Its pharmacotherapeutic group is: Non- steroidal anti-inflammatory and anti-rheumatic products. Derivatives of acetic acid and related substances. (ATC Code: M01AB16). Aceclofenac's mechanism of action is largely based on inhibiting prostaglandin synthesis. Aceclofenac is a potent inhibitor of the enzyme cyclooxygenase, which is involved in producing prostaglandins. After oral administration, Aceclofenac is rapidly and completely absorbed as unaltered drug. Maximum plasma concentrations are reached approximately 1.25 to 3.00 hours after administration. Aceclofenac penetrates into the synovial fluid, where its concentrations reach approximately 57% of the plasma concentrations. The volume of distribution is approximately 25 L.

The plasma half-life is around 4 hours. Aceclofenac shows high protein binding (>99%). Aceclofenac mainly circulates in the form of unaltered drug. The principal metabolite found in the plasma is 4'-hydroxyaceclofenac. Approximately two thirds of the dose administered is excreted through the urine, predominantly in the form of hydroxymetabolites.

The results from preclinical studies performed with aceclofenac are congruent with those expected in non-steroidal anti-inflammatory drugs. The main target organ was the gastrointestinal tract. No unexpected findings were recorded.
Aceclofenac was considered not to have any mutagenic activity in three in vitro studies and in one in vivo study in rats. However, in a study in rabbits treatment with aceclofenac (10 mg/kg/day) caused a series of morphological alterations in some foetuses.
Teratogenesis studies in rats were negative and presented no abnormalities. Aceclofenac was not found to be carcinogenic in mice or rats.

CONTRAINDICATIONS:
Not to be given to those patients who have history of:
- Stroke; cerebrovascular accident (CVA)
- Heart attack: Myocardial infarction (MI)
- Coronary Artery bypass graft (CABG) and recent revascularization procedures
- Uncontrolled hypertension
- Congestive Heart Failure (CHF) NYHA II-IV, ischaemic heart disease, peripheral arterial disease and/or cerebrovascular disease
- Gastrointestinal bleeding or perforation, active or history of recurrent peptic ulcer / haemorrhage or to patients with in whom one is suspected.

Not to be given to patients:
- with known hypersensitivity to any of the excipients of this medicinal product
- with bleeding or a blood clotting disorder
- with severe renal failure or severe liver failure
- during the third trimester of pregnancy and lactation, or to women who are planning to become pregnant.
- in whom acetylsalicylic acid or non-steroidal anti-inflammatory drugs trigger asthma attacks, acute rhinitis or urticaria, or to patients with hypersensitivity to these drugs.

DOSAGE AND ADMINISTRATION:
Aceclofenac (Airtal®) tablet should not be taken with an empty stomach. To be taken with or after food.
When Aceclofenac (Airtal®) was administered to fasting and fed healthy volunteers only the rate and not the extent of aceclofenac absorption was affected.

Aceclofenac (Airtal®) tablet should be taken whole with a sufficient amount of liquid.

Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.

Adults:
- The recommended dose is 200 mg daily, taken as two separate 100 mg doses, one tablet in the morning and one in the evening.

Children:
- There are no clinical data regarding the use of Aceclofenac (Airtal®) in children and therefore it is not recommended for use in children.

For Elderly:
- The pharmacokinetics of Aceclofenac (Airtal®) is not affected in elderly patients, so it is therefore not considered necessary to alter the dose or the frequency of administration. However, as with any other non-steroidal anti-inflammatory drug, precautions must be taken when treating elderly patients which should be monitored regularly for gastrointestinal bleeding. These patients are at increased risk of the serious consequences of adverse reactions, have a greater chance of developing cardiovascular disorders and renal or liver impairment, and are often taking concomitant medication.

For patients with Renal Impairment:
- There is no evidence to suggest that the dosage of Aceclofenac (Airtal®) should be altered in patients with minor renal impairment, but as with other NSAIDs caution should be exercised.

For patients with Liver Impairment:
- Some evidence suggests that the dose of Aceclofenac (Airtal®) must be reduced in patients with liver impairment, with a recommended dose of 100 mg/day.

SPECIAL PRECAUTIONS AND WARNINGS FOR USE:
Undesirable effects may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.

The use of Aceclofenac (Airtal®) with concomitant NSAIDs including cyclooxygenase-2 selective inhibitors should be avoided.

Elderly:
The elderly have an increased frequency of adverse reactions to NSAIDs especially gastrointestinal bleeding and perforation which may be fatal.

Respiratory disorders:
Caution is required if administered to patients suffering from, or with a previous history of, bronchial asthma since NSAIDs have been reported to precipitate bronchospasm in such patients.

Cardiovascular, Renal and Hepatic Impairment:
The administration of an NSAID may cause a dose dependent reduction in prostaglandin formation and precipitate renal failure. Patients at greatest risk of this reaction are those with impaired renal function, cardiac impairment, liver dysfunction, those taking diuretics or recovering from major surgery, and the elderly. The importance of prostaglandins in maintaining renal blood flow should be taken into account in these patients.
Renal function should be monitored in these patients.

Renal:
Patients with mild to moderate renal impairment should be kept under surveillance, since the use of NSAIDs may result in deterioration of renal function. The lowest effective dose should be used and renal function monitored regularly. Effects on renal function are usually reversible on withdrawal of Aceclofenac (Airtal®).

Hepatic:
If abnormal liver function tests persist or worsen, clinical signs or symptoms consistent with liver disease develop or if other manifestations occur (eosinophilia, rash), Aceclofenac (Airtal®) should be discontinued. Close medical surveillance is necessary in patients suffering from mild to moderate impairment of hepatic function. Hepatitis may occur without prodromal symptoms. Use of Aceclofenac (Airtal®) in patients with hepatic porphyria may trigger an attack.

Cardiovascular and cerebrovascular effects:
Appropriate monitoring and advice are required for patients with a history of hypertension and/or mild to moderate congestive heart failure as fluid retention and oedema have been reported in association with NSAID therapy.

Patients with congestive heart failure (NYHA-I) and patients with significant risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking) should only be treated with aceclofenac (Airtal®) after careful consideration. As the cardiovascular risks of aceclofenac (Airtal®) may increase with dose and duration of exposure, the shortest duration possible and the lowest effective daily dose should be used. The patient's need for symptomatic relief and response to therapy should be re-evaluated periodically.

Aceclofenac (Airtal®) should also be administered with caution and under close medical surveillance to patients with a history of cerebrovascular bleeding.

Gastrointestinal bleeding, ulceration and perforation:
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.

Close medical surveillance is imperative in patients with symptoms indicative of gastro-intestinal disorders involving either the upper or lower gastrointestinal tract, with a history suggestive of gastro-intestinal ulceration, bleeding or perforation, with ulcerative colitis or with Crohn's disease, or haematological abnormalities, as these conditions may be exacerbated

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, 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.

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 systemic corticosteroids, anticoagulants such as warfarin, selective serotonin-reuptake inhibitors or antiplatelet agents such as aspirin.

When GI bleeding or ulceration occurs in patients receiving aceclofenac (Airtal®), the treatment should be withdrawn.

SLE and mixed connective tissue disease:
In patients with systemic lupus erythematosus (SLE) and mixed connective tissue disorders there may be an increased risk of aseptic meningitis.

Dermatological:
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. Patients appear to be at highest risk for 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. Aceclofenac (Airtal®) should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

Exceptionally, varicella can trigger serious cutaneous and soft tissues infections 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 aceclofenac (Airtal®) in case of varicella.

Hypersensitivity reactions:
As with other NSAIDs, allergic reactions, including anaphylactic/anaphylactoid reactions, can also occur without earlier exposure to the drug.

Haematological:
Aceclofenac (Airtal®) may reversibly inhibit platelet aggregation.

Long-term treatment:
All patients who are receiving NSAIDs should be monitored as a precautionary measure e.g. renal, hepatic function (elevation of liver enzymes may occur) and blood counts.

EFFECTS OF ABILITY TO DRIVE AND USE OF MACHINERY:
If you suffer from dizziness, fainting, vertigo or any other central nervous system disorder, do not use dangerous tools or machinery while you are taking Aceclofenac (Airtal®).

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Proof: 6	Artwork Information Panel	almirall
Description: PIL Airtal 100mg coated tab SG Mock up		
Regulatory text: Airtal film coated tablet PI-Prop16Aug2021 (1-2)		
Item Number: 00000000	**Material size:** 316 x 411 mm	
Designer: Thinkinpress	**Date:** 23.05.2022	
Fonts: Graphik Regular / *Regular Italic* / **Semibold** / ***Semibold Italic*** *"8pt in Graphic Font equal to 9pt on Times New Roman"*	**Minimum Font Size:** 8 pt **Prefixes (eg.Lot/Exp) Font Size:** **Leading:** 3 mm	
Manufacturer's Technical check Manufacturer confirms the printability and technical compliance of this packaging material for correct use during packaging process. ☐ Date and Signature		

Printing Colours	Non Printing Colours	Inline control code
P Black	Die Cut	
	Colour reference in PMS Bridge Equate with CMYK	

INTERACTION WITH OTHER MEDICINAL PRODUCTS:
Lithium and Cardiac Glycosides, like Digoxin: Aceclofenac (Airtal®), like many non-steroidal anti-inflammatory drugs, may increase the plasma concentrations of lithium and Digoxin. The combination should be avoided unless frequent monitoring of lithium and digoxin levels can be performed.
Diuretics: Studies on animals show the possibility that Aceclofenac (Airtal®), like other non-steroidal anti-inflammatory drugs, could interfere with the natriuretic action of diuretics. Diuretics can increase the risk of nephrotoxicity of NSAIDs. This property could be clinically significant in patients with hypertension or impaired cardiac function.When concomitant administration with potassium sparing diuretics is employed, serum potassium should be monitored.
Antihypertensives: Non-steroidal anti-inflammatory drugs (NSAIDs) may reduce the effect of antihypertensives. The risk of acute renal insufficiency, which is usually reversible, may be increased in some patients with compromised renal function (e.g. dehydrated patients or elderly patients) when ACE- inhibitors or angiotensin II receptor antagonists are combined with NSAIDs. Therefore, the combination of Aceclofenac (Airtal®) with antihypertensives should be administered with caution, especially in the elderly. Patients should be adequately hydrated and consideration should be given to monitoring of renal function after initiation of concomitant therapy, and periodically thereafter.
Effects of Aceclofenac (Airtal®) were not observed on the control of blood pressure when it was administered together with bendroflumethiazide, however it is not possible to rule out interaction with other antihypertensive drugs.
Anticoagulants: Like other non-steroidal anti-inflammatory drugs, Aceclofenac (Airtal®), may enhance the action of anticoagulants due to a possible inhibition of platelet aggregation. Patients who received combined treatment with anticoagulants and Aceclofenac (Airtal®) must be adequately monitored.
Antiplatelet antiaggregants: Aceclofenac (Airtal®), like many non-steroidal anti-inflammatory drugs (NSAIDs) may increase the risk of gastrointestinal bleeding when combined with antiplatelet antiaggregants.
Oral antidiabetic: The possibility of altering the dose of hypoglycaemic agents must be taken into account when Aceclofenac (Airtal®) is administered.
Methotrexate: Precautions must be taken if non-steroidal anti-inflammatory drugs and Methotrexate are both administered within an interval of less than 24 hours, because non-steroidal anti-inflammatory drugs can increase the plasma concentration of Methotrexate, causing greater toxicity.
Corticosteroids: The risk of gastrointestinal ulceration or bleeding may be increased when Aceclofenac (Airtal®) is administered with corticosteroids.
Other anti-inflammatory drugs: Avoid concomitant treatment with Acetylsalicylic Acid and other non-steroidal anti-inflammatory drugs as this may increase the frequency of the side effects, including gastrointestinal bleeding.
Selective serotonin reuptake inhibitors (SSRIs): Aceclofenac (Airtal®), like many non-steroidal anti-inflammatory drugs (NSAIDs) could increase the risk of gastrointestinal bleeding when it is combined with SSRIs.
Cyclosporine, tracolimus: The effect of non-steroidal anti-inflammatory drugs on the renal prostaglandin may increase the nephrotoxicity of Cyclosporine or tracolimus. During combination therapy it is therefore important to carefully monitor renal function.
Zidovudine: When non-steroidal anti-inflammatory drugs (NSAIDs) like Aceclofenac (Airtal®) are given with zidovudine there is an increased risk of haematological toxicity. There are indications of an increased risk of haemoarthroses and haematoma in HIV(+) haemophiliacs receiving concurrent treatment with zidovudine and ibuprofen.
Mifepristone: NSAIDs should not be used for 8-12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone.
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.

PREGNANCY AND LACTATION:
PREGNANCY and FERTILITY:

Pregnancy:
There is no information on the use of Aceclofenac (Airtal®) during pregnancy. Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/fetal development. Data from epidemiological studies suggest an increased risk of miscarriage, cardiac malformation or gastroschisis after use of prostaglandin synthesis inhibitor in early pregnancy. The absolute risk for cardiovascular malformation was increased from less than 1%, up to approximately 1.5 %. The risk is believed to increase with dose and duration of therapy.

In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryo-foetal lethality. In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period. During the first and second trimester of pregnancy, Aceclofenac (Airtal®) should not be given unless clearly necessary. If Aceclofenac (Airtal®) 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.

Use of NSAIDs at about 20 weeks gestation or later in pregnancy may cause foetal renal dysfunction leading to oligohydramnios and in some cases, neonatal renal impairment. These adverse outcomes are seen, on average, after days to weeks of treatment, although oligohydramnios has been infrequently reported as soon as 48 hours after NSAID initiation. Oligohydramnios is often, but not always, reversible with treatment discontinuation.

During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may expose the foetus to:
- cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension);
- renal dysfunction, which may progress to renal failure with oligo-hydroamniosis;

the mother and the neonate, at the end of pregnancy, to:
- possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses.
- inhibition of uterine contractions resulting in delayed or prolonged labour.

Consequently, you should not take Aceclofenac (Airtal®) during the third trimester of pregnancy.

Fertility:
The use of Aceclofenac (Airtal®) may impair female fertility and is not recommended in women attempting to conceive. In women who have difficulties conceiving or who are undergoing investigation of infertility, withdrawal of Aceclofenac (Airtal®) should be considered.

LACTATION: There is no information on the secretion of Aceclofenac (Airtal®) to breast milk, there was however no notable transfer of radio labelled (14C) aceclofenac to the milk of lactating rats.
The use of Aceclofenac (Airtal®) should therefore be avoided in pregnancy and lactation unless the potential benefits to the other outweigh the possible risks to the foetus.

UNDESIRABLE EFFECTS:
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. Nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia, abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease and gastritis have been reported following administration. Pancreatitis has been reported very rarely.

Hypersensitivity: Hypersensitivity reactions have been reported following treatment with NSAIDs. These may consist of (a) non- specific allergic reactions and anaphylaxis (b) respiratory tract reactivity reactions comprising asthma, aggravated asthma, bronchospasm or dyspnoea, or (c) assorted skin disorders, including rashes of various types, pruritus, urticaria, purpura, angiodema and, more rarely exfoliative and bullous dermatoses (including epidermal necrolysis and erythema multiforme).

Cardiovascular disorders: Oedema, hypertension and cardiac failure have been reported in association with NSAID treatment.

Aceclofenac is both structurally related and metabolised to diclofenac for which a greater amount of clinical and epidemiological data consistently point towards an increased risk of general arterial thrombotic events (for example myocardial infarction or stroke, particularly at high doses or in long treatment). Epidemiological data has also found an increased risk of acute coronary syndrome and myocardial infarction associated with the use of aceclofenac.

Exceptionally, occurrence of serious cutaneous and soft tissues infections complications during varicella has been reported in association with NSAID treatment.

Other adverse reactions reported include:

Renal: interstitial nephritis, renal failure.
Neurological and special senses: optic neuritis, reports of aseptic meningitis (especially in patients with existing auto immune disorders, such as systemic lupus erythematosus, mixed connective tissue disease), with symptoms such as stiff neck, headache, nausea, vomiting, fever or disorientation, confusion, hallucinations, malaise and drowsiness have been reported.

Haematological: agranulocytosis, aplastic anaemia.

Dermatological: Bullous reactions including Stevens Johnson Syndrome and Toxic Epidermal Necrolysis (very rare). Photosensitivity.

If serious adverse reactions occur, Aceclofenac (Airtal®) should be withdrawn.

The following is a table of adverse reactions reported during clinical studies and after authorization, grouped by System-Organ Class and estimated frequencies. 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 SOC	**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**
Blood and lymphatic system disorders			Anaemia	Bone Marrow depression Granulocytopenia Thrombocytopenia Neutropenia Haemolytic anaemia
Immune system disorders			Anaphylactic reaction (including shock) Hypersensitivity	
Metabolism and nutrition disorders				Hyperkalemia
Psychiatric disorders				Depression Abnormal dreams Insomnia
Nervous system disorders	Dizziness			Paraesthesia Tremor Somnolence Headache Dysgeusia (abnormal taste)
Eye disorders			Visual disturbance	
Ear and labyrinth disorders				Vertigo Tinnitus
Cardiac disorders			Cardiac failure	Palpitations
Vascular disorders			Hypertension	Flushing Hot flush Vasculitis
Respiratory, thoracic and mediastinal disorders			Dyspnoea	Bronchospasm Stridor
Gastrointestinal disorders	Dyspepsia Abdominal pain Nausea Diarrhoea	Flatulence Gastritis Constipation Vomiting Mouth ulceration	Melaena Gastrointestinal haemorrhage Gastrointestinal ulceration	Stomatitis Intestinal perforation Exacerbation of Crohn's disease and Colitis Ulcerative Haematemesis Pancreatitis
Hepatobiliary disorders	Hepatic enzyme increased			Hepatic injury (including hepatitis) Jaundice Blood alkaline phosphatase increased
Skin and subcutaneous tissue disorders		Pruritus Rash Dermatitis Urticaria	Angioedema	Purpura Severe mucocutaneous skin reaction (including Stevens Johnson Syndrome and Toxic Epidermal Necrolysis)
Renal and urinary disorders		Blood urea increased Blood creatinine increased		Renal failure Nephrotic syndrome
General disorders and administration site conditions				Oedema Fatigue Cramps in legs
Investigations				Weight increase

OVERDOSAGE:
No data is available regarding the consequences of an overdose of Aceclofenac (Airtal®) in humans. Symptoms of an overdose of Aceclofenac (Airtal®) include headache, nausea, vomiting, epigastric pain, gastrointestinal irritation, gastrointestinal bleeding, rarely diarrhoea, disorientation, excitation, coma, drowsiness, dizziness, tinnitus, hypotension, respiratory depression, fainting, occasionally convulsions. In cases of significant poisoning acute renal failure and liver damage are possible. The treatment of acute intoxication by non-steroidal anti-inflammatory drugs essentially consists of supportive and symptomatic measures:
- Patients should be treated symptomatically as required.
- Within one hour of ingestion of a potentially toxic amount, activated charcoal should be considered. Alternatively, in adults, gastric lavage should be considered within one hour of ingestion of a potentially life-threatening overdose.
- Specific therapies such as dialysis or haemoperfusion are probably of no help in eliminating NSAIDs due to their high rate of protein binding and extensive metabolism.
- Good urine output should be ensured.
- Renal and liver function should be closely monitored.
- Patients should be observed for at least four hours after ingestion of potentially toxic amounts.
- In case of frequent or prolonged convulsions, patients should be treated with intravenous diazepam.
- Other measures may be indicated by the patient's clinical condition.
- Management of acute poisoning with oral aceclofenac essentially consists of supportive and symptomatic measures for complications such as hypotension, renal failure, convulsions, gastro-intestinal irritation, and respiratory depression.

CAUTION:
No incompatibilities with other medicinal products have been described.

STORAGE:
Store at temperatures not exceeding 30°C.
Do not use this medicine after the expiry date which is stated on the carton.

SIN15700P

AVAILABILITY:
Box of 10's, 20's, 40's, 50's and 100's in Aluminium/ Aluminium Blisters.

Manufactured by:
INDUSTRIAS FARMACÉUTICAS ALMIRALL, S.A.
Ctra. De Martorell, 41-61, 08740 Sant Andreu de la Barca – Barcelona, Spain.

Product Registration Holder
- **Singapore**
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  6 Tagore Drive, #04-13 Tagore Building, 787623, Singapore.

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Proof: 6	Artwork Information Panel	almirall
Description: PIL Airtal 100mg coated tab SG Mock up		Printing Colours: P Black; Non Printing Colours: Die Cut; Colour reference in PMS Bridge Equate with CMYK; Inline control code
Regulatory text: Airtal film coated tablet PI-Prop16Aug2021 (2-2)		
Item Number: 00000000	**Material size:** 316 x 411 mm	
Designer: Thinkinpress	**Date:** 23.05.2022	
Fonts: Graphik Regular / *Regular Italic* / **Semibold** / ***Semibold Italic*** *"8pt in Graphic Font equal to 9pt on Times New Roman"*	**Minimum Font Size:** 8 pt **Prefixes (eg.Lot/Exp) Font Size:** **Leading:** 3 mm	
Manufacturer's Technical check Manufacturer confirms the printability and technical compliance of this packaging material for correct use during packaging process. ☐ Date and Signature		