

Importation of Turkish Ibuprofen for Children up to 11 years (Orange Flavour) due to the current shortage of Canadian-authorized Pediatric Analgesic Products

As the country experiences increased consumer-driven demand for ibuprofen products for infants and children, manufacturers are taking all possible measures to ensure product availability, however a shortage continues to be experienced in Canada.

Health Canada has permitted the exceptional, temporary importation and sale of ibuprofen products under the brand name Pedifen® which is manufactured and licenced in Turkey, by Atabay Pharmaceuticals and Fine Chemicals (Atabay Ilac Fabrikasi, A.S.), a pharmaceutical manufacturer that already produces and exports active pharmaceutical ingredients (APIs) for the Canadian market. This product for children up to 11 years is permitted for sale and distribution to hospitals and retail outlets **in Alberta only**.

IMPORTANT ACTIONS REQUIRED

- **Alberta Health – Disseminate this communication to the Alberta College of Pharmacy**
- **Alberta College of Pharmacy – distribute this communication to Pharmacists**
- **Pharmacists – review differences in the dosing device to provide advice to product purchasers (parents/caregivers) to avoid medication errors. See important information below regarding this approval and its restriction to Alberta market only.**
- **Pharmacists and purchasers may contact MHCare Medical directly for questions or concerns 1-888-834-1871**

Communication for Pharmacists:

Health Canada has permitted the exceptional, temporary importation and sale of ibuprofen products under the brand name Pedifen® which is manufactured and licenced in Turkey, by Atabay Pharmaceuticals and Fine Chemicals (Atabay Ilac Fabrikasi, A.S.), a pharmaceutical manufacturer that already produces and exports active pharmaceutical ingredients (APIs) for the Canadian market. This product for children up to 11 years is permitted for sale and distribution to hospitals and retail outlets **in Alberta only**.

In order to adequately communicate information to purchasers/caregivers, pharmacists should be aware that Pedifen® is sold with different inactive ingredients, including sunset yellow E110 dye and a different dosing device with different graduations. Note, this product is alcohol free. Please see Appendices for pictures of the labels and dosing devices.

Pharmacists with questions can contact MHCare Medical at 1-888-834-1871. Hours of Operation are Monday – Friday 9am - 4:30pm MST or see <https://www.pedifen.info/communication>.

Information on the imported product					
Brand name	Dosage form, strength, and route of administration	Product description and packaging	Country of authorization and identifying code	Authorization holder	DEL holder/ Importer in Canada

Pedifen®	Oral suspension (orange flavour), ibuprofen 20 mg/mL	Each glass amber bottle with child-resistant cap contains 100 mL packaged in a paper box. Each box contains a plastic dosing spoon.	Turkey (License 176/23)	Atabay Ilac Fabrikasi, A.S.	MHCare Medical Corporation
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The Pedifen® product has some of the **same** product characteristics as the Canadian-authorized product that are relevant to the end user, including active ingredient, dosage form, indications, dosing instructions and route of administration. The product, however, **differs** in the following ways: brand, flavour, container, inactive ingredients, dosing device, and storage. These differences may lead to allergies or hypersensitivities that should be considered and monitored as part of patient assessment, counselling, monitoring and follow up.

Healthcare professionals are advised that aspects of the inner and outer labels and packaging of the Pedifen® branded product may differ from current pediatric products in Canada. Proper selection of the intended product must be verified to avoid confusion with other products and prevent medication errors.

Comparison of the Pedifen® branded product and Canadian authorized product provided in Table 1.

Table 1.

Brand	Pedifen® For Children					Children’s Motrin® (Canadian authorized product)				
Strength	Ibuprofen 100mg/5 mL					Ibuprofen 100 mg/5mL				
Flavour	Orange					Fruit flavour				
Volume / Package Size	100 mL					100 mL				
Container /Closure	Glass amber bottle with child resistant cap					Plastic bottle with child resistant cap				
Inactive Ingredients	Agar, citric acid monohydrate, glycerine, kaolin, methylparahydroxybenzoate (E218), orange aroma, polysorbate, propyl hydroxybenzoate (E216), purified water, sucrose, sunset yellow E 110					Acesulfame potassium, citric acid, D&C yellow no.10, DF&C red no. 40, flavour, glycerin, polysorbate 80, pregelatinized corn starch, purified water, sodium benzoate, sucrose, xanthan gum				
Dosing Table by Weight	Weight (lb)	Weight (kg)	Age Grp (yrs)	Single Dose (mg)	Max Daily (mg)	Weight (lb)	Weight (kg)	Age Grp (yrs)	Single Dose (mg)	Max Daily (mg)
	72-95	32-43.9	11	300	1200	72-95	32-43.9	11	300	1200
	60-71	27-31.9	9-10	250	1000	60-71	27-31.9	9-10	250	1000
	48-59	22-26.9	6-8	200	800	48-59	22-26.9	6-8	200	800
	36-47	16-21.9	4-5	150	600	36-47	16-21.9	4-5	150	600
	24-35	11-15.9	2-3	100	400	24-35	11-15.9	2-3	100	400
Dosing Device	Spoon with graduations					Cup with graduations				
Storage	Store in a dry place at room temperature under 25 °C					Store at room temperature (15-30 °C)				

Directions for use	<p>● Shake well before using ● Find right dose on chart below. Dosing spoon - full spoon=5mL; 1st line=2.5mL; 2nd line=1.25mL whenever possible dose by weight. ● Repeat dose every 6-8 hours while symptoms last. ● Do not give more than 4 times in 24 hours.</p>	<p>■ Use weight to dose; otherwise use age ■ shake well before use and ensure all contents of dosage cup are taken ■ doses may be repeated every 6-8 hours while symptoms persist, up to 4 doses/day, or as directed by a doctor.</p> <p>■ Shake well before using ■ Use enclosed dosage cup ■ if possible, dose according to body weight ■ single dose may be repeated every 6-8 hours as needed ■ Do not give more than 4 doses in 24 hours, unless directed by a doctor ■ Use the lowest effective dose for the shortest duration.</p>
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Dosing and Directions for Use

The concentration of this product is 100 mg/5mL, which is the same concentration as the product on the Canadian market; therefore, a single dosage and the maximum daily dosage aligns with Canadian products. Please use the chart below and dose based on weight. Repeat dose every 6-8 hours while symptoms last. Do not give more than 4 times in 24 hours. Do not take more than directed. The dosing device provided with the product allows for the measure of 1.25mL (base of the spoon), 2.5mL (first line) and 5mL (full spoon) aliquots. See Appendix 2 for a picture of the dosing spoon.

Weight (lbs)	Weight (kg)	Age (yrs)	Single Dose (mg)	Single Dose (mL)	Max Daily (mg)	Max Daily (mL)
24-35	11.0-15.9	2-3	100	5	400	20
36-47	16.0-21.9	4-5	150	7.5	600	30
48-59	22.0-26.9	6-8	200	10	800	40
60-71	27.0-31.9	9-10	250	12.5	1000	50
72-95	32.0-43.9	11	300	15	1200	60

Questions or concerns

Parents, and caregivers with questions can contact their local pharmacist or MHCare Medical at 1-888-834-1871. Hours of Operation are Monday – Friday 9am - 4:30pm MST.

Adverse Events

Adverse drug reactions associated with the use of Pedifen should be reported to MHCare Medical at 1-888-834-1871 or to Health Canada at <https://www.canada.ca/en/health-canada/services/drugs-healthproducts/medeffect-canada/adverse-reaction-reporting.html> or by calling toll-free at 1-866-234-2345.

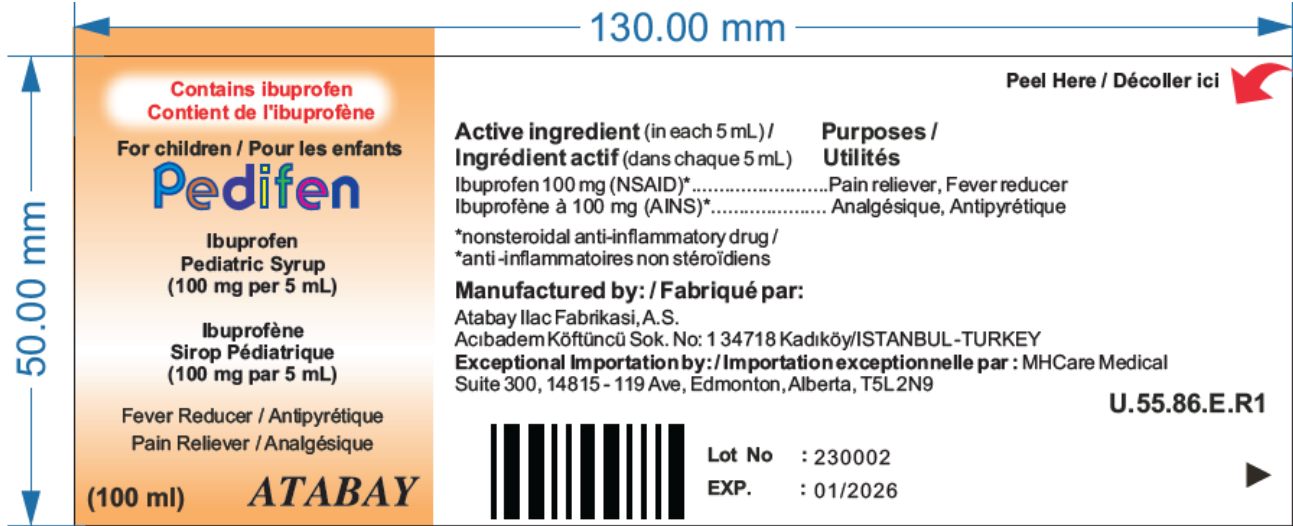
Sincerely,



Keri Shannon
Chief Operating Officer

MHCare Medical

Appendix 1: Pedifen® Product labels
Bottle Label



130.00 mm

50.00 mm

Peel Here / Décoller ici

Contains ibuprofen / Contient de l'ibuprofène

For children / Pour les enfants

Pedifen

Ibuprofen Pediatric Syrup (100 mg per 5 mL)

Ibuprofène Sirop Pédiatrique (100 mg par 5 mL)

Fever Reducer / Antipyrétique

Pain Reliever / Analgésique

(100 ml) ATABAY

Active ingredient (in each 5 mL) / Ingrédient actif (dans chaque 5 mL)

Ibuprofen 100 mg (NSAID)* Pain reliever, Fever reducer
Ibuprofène à 100 mg (AINS)* Analgésique, Antipyrétique

*nonsteroidal anti-inflammatory drug / *anti-inflammatoires non stéroïdiens

Purposes / Utilités

Manufactured by: / Fabriqué par:

Atabay Ilac Fabrikasi, A.S.
Acıbadem Köftüncü Sok. No: 1 34718 Kadıköy/ISTANBUL - TURKEY

Exceptional Importation by: / Importation exceptionnelle par: MHCare Medical
Suite 300, 14815 - 119 Ave, Edmonton, Alberta, T5L2N9

U.55.86.E.R1

Lot No : 230002

EXP. : 01/2026

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Uses / Usages •Reduces fever •Temporarily relieves mild aches and pains due to •common cold or flu •headaches •sore throat •toothache •muscle sprains and strains / •Réduit la fièvre •Soulage temporairement des douleurs légères associées • au rhume et à la grippe •aux maux de tête • aux maux de gorge •aux maux des dents •entorses et foulures musculaires

Warnings / Mises en garde

Stomach bleeding warning / Avertissement - saignement gastrique This product may cause stomach bleeding. Symptoms may include: •feeling faint, •vomiting blood, •bloody or black stools. The chance of stomach bleeding is higher if your child: •has had stomach ulcers or bleeding problems, •take a blood thinner or steroid drug, •take with other drugs containing an NSAID like acetylsalicylic acid (ASA), ibuprofen, naproxen, or prescription anti-inflammatory drugs. / Ce produit peut causer des saignements gastriques. Les symptômes peuvent inclure: •perte de connaissance, •vomissement de sang, •selles noires ou sanglantes. Le risque de saignement gastrique est plus élevé si votre enfant: •a déjà eu des ulcères d'estomac ou des problèmes de saignements gastriques, •prend des anticoagulants ou des stéroïdes, •prend d'autres médicaments contenant un AINS comme l'acide acétylsalicylique (AAS), l'ibuprofène, le naproxène ou des anti-inflammatoires sur ordonnance

Allergy alert / Alerte aux allergies Ibuprofen may cause a severe allergic reaction, especially in people allergic to ASA. Stop use and get medical help right away if your child have •severe itching •hives •swelling of eyes and mouth •skin blisters •difficulty breathing / L'ibuprofène peut causer une grave réaction allergique, en particulier chez les personnes allergiques à l'AAS. Cessez l'emploi et consultez immédiatement un médecin si votre enfant a • des démangeaisons sévères • de l'urticaire • un gonflement des yeux et de la bouche • des éruptions cutanées • de la difficulté à respirer

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Do not use / Ne pas utiliser • If your child is allergic to ibuprofen, ASA, salicylates, NSAIDs • right before or after heart surgery. / • Si votre enfant est allergique à l'ibuprofène, à l'AAS, aux salicylates, aux AINS • immédiatement avant ou après une chirurgie cardiaque.

Ask a doctor or pharmacist before use if your child / Consultez un médecin ou un pharmacien avant l'utilisation si votre enfant • has: • ulcers or stomach bleeding, • high blood pressure, • heart disease, • diabetes • liver or kidney disease, • any other serious condition • take any other medication especially daily low-dose ASA (81 to 325 mg) / • a: • des ulcères ou saignements gastriques, • de l'hypertension, • une cardiopathie, • du diabète • une maladie du foie ou du rein, • un autre état grave • prend d'autres médicaments, notamment une faible dose quotidienne d'AAS (81 à 325 mg)

When using this product / Lorsque vous utilisez ce produit • take with food or milk if stomach upset occurs. • the risk of heart attack or stroke may increase if you use more than directed or for longer than directed. / • En présence de maux d'estomac prendre avec des aliments ou du lait • Le risque de crise cardiaque ou d'accident vasculaire cérébral peut augmenter si votre enfant dépasse la dose recommandée ou prend ce produit pendant plus longtemps que la période recommandée

Stop use and ask a doctor if/ Cessez d'utiliser et consultez un médecin si • your child has signs of stomach bleeding (see Stomach bleeding warning above) • pain gets worse or lasts more than 5 days • fever gets worse or lasts more than 3 days • sore throat pain lasts for more than 2 days • any new symptoms appear / • l'enfant présente des signes de saignement gastrique (voir l'avertissement concernant les saignements gastriques) • la douleur s'aggrave ou dure plus de 5 jours • la fièvre s'aggrave ou dure plus de 3 jours • la douleur du mal de gorge dure plus de 2 jours • de nouveaux symptômes apparaissent

● **Keep out of reach of children / Garder hors de la portée des enfants.** In case of overdose, call a poison control centre or get medical help right away / En cas de surdose, appeler un centre antipoison ou obtenir une assistance médicale immédiate.

Directions / Mode d'emploi • Shake well before using • Find right dose on chart below. Dosing spoon - full spoon=5mL; 1st line=2.5mL; 2nd line=1.25mL whenever possible dose by weight. • Repeat dose every 6-8 hours while symptoms last. • **Do not** give more than 4 times in 24 hours. / • bien agiter avant chaque utilisation • Trouver la bonne dose dans le tableau ci-dessous. Cuillère doseuse - cuillère pleine=5mL; 1ère ligne=2.5mL; 2ème ligne = 1.25mL. Si possible, établir la dose en fonction du poids • Répéter la dose toutes les 6 à 8 heures tant que les symptômes durent. • **Ne pas** donner plus de 4 fois en 24 heures.

Weight (lb) Poids (lb)	Weight (kg) Poids (kg)	Age (yr) Âge (ans)	Dose (mL)
24-35	11-15.9	2-3	5
36-47	16-21.9	4-5	7.5
48-59	22-26.9	6-8	10
60-71	27-31.9	9-10	12.5
72-95	32-43.9	11	15

Other information / Autres renseignements

• Store in a dry place, at a room temperature under 25°C. / Conserver dans un endroit sec, à une température ambiante inférieure à 25°C. • Child resistant package. Do not use if tamper evident seal is broken. / Emballage à l'épreuve des enfants. Ne pas utiliser si le sceau inviolable est brisé

Inactive ingredients / Ingrédients inactifs agar, citric acid monohydrate, glycerine, kaolin, methylparahydroxybenzoate (E218), orange aroma, polysorbate, propyl hydroxybenzoate (E216), purified water, sucrose, sunset yellow E 110 / agar, acide citrique monohydraté, eau purifiée, glycérine, jaune orangé E110, kaolin, méthyl parahydroxybenzoate (E218), polysorbate, propyle hydroxybenzoate (E216), saccharose, saveur d'orange,

Questions? 1.888.834.1871 www.mhcaremedical.com

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Outer Carton (Paper box)



Child resistant package. Do not use if tamper evident seal is broken. / Emballage à l'épreuve des enfants. Ne pas utiliser si le sceau inviolable est brisé.

Drug Facts / Info-médicament

Active ingredient (in each 5 mL) / Ingrédient actif (dans chaque 5 mL)	Purposes / Utilités
Ibuprofen 100 mg (NSAID).....	Pain reliever, Fever reducer
Ibuprofène à 100 mg (AINS).....	Analgésique, Antipyrétique

*nonsteroidal anti-inflammatory drug /
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Do not use/ Ne pas utiliser •If your child is allergic to ibuprofen, ASA, salicylates, NSAIDs •right before or after heart surgery. / •Si votre enfant est allergique à l'ibuprofène, à l'ASA, aux salicylates, aux AINS •immédiatement avant ou après une chirurgie cardiaque.

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Inactive ingredients / Ingrédients inactifs

agar, citric acid monohydrate, glycerine, kaolin, methylparahydroxybenzoate (E218), orange aroma, polysorbate, propyl hydroxybenzoate (E216), purified water, sucrose, sunset yellow E 110 / agar, acide citrique monohydraté, eau purifiée, glycérine, jaune orangé E110, kaolin, méthyl parahydroxybenzoate (E218), polysorbate, propyle hydroxybenzoate (E216), saccharose, saveur d'orange,

Questions? 1.888.834.1871
www.mhcaremedical.com

Manufactured by: / Fabriqué par:

Atabay Ilac Fabrikası, A.S.

Acıbadem Köftüncü Sok. No: 1 34718

Kadıköy/ISTANBUL-TURKEY

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Exceptional Importation by: / Importation exceptionnelle par: MHCare Medical

Suite 300, 14815 - 119 Ave, Edmonton, Alberta, T5L 2N9

Appendix 2: Dosing Device

