

Update to Pharmacy Teams on Importation Liquid Pediatric Acetaminophen with Child-Resistant Packaging

On January 26, 2023, Health Canada provided Alberta Health with a no objection letter for the importation of liquid pediatric acetaminophen produced by Atabay Pharmaceuticals under the brand name Parol.

Parol is a 24 mg/ml oral suspension, which comes in a 150 ml size child-resistant glass bottle with a graduated spoon and in an orange flavor. It is important to know that this differs from the Canadian-authorized product which comes in a concentration of 32 mg/ml and uses a different dosing device.

As part of the Risk Mitigation Plan established to account for the difference in concentration and the resulting change to the dose which would be administered to a child for treatment of pain and/or fever, **Parol MUST be kept behind the counter, in the dispensary, for storage and for sale in community pharmacies.**

As part of the Risk Mitigation Plan, which was the basis under which the exceptional importation of this drug was approved by Health Canada, **pharmacists are expected to provide counselling and education to parents/caregivers on the safe and correct usage of Parol**, as well as the product differences from Canadian-authorized supply.

Again, these measures are required as part of the Risk Mitigation Plan approved by Health Canada to import this product for use in Alberta. The Alberta College of Pharmacy will be providing more detailed communication to pharmacy teams in the near future through guidance to the professions.

Once the first shipment of product arrives in Alberta, pharmacy wholesale distributors will begin to bring in inventory for sale to community pharmacies. As previously communicated to the public, the product will be priced at wholesale similarly to other acetaminophen products which are Canadian authorized.

The suggested retail price of 150 mL of Parol is \$11.99.

Further communication will be sent to pharmacies once the first shipment arrives in Alberta on anticipated order dates, financial terms, return policy and operational specifics.

For assistance with benefit or claim inquiries, please contact an Alberta Blue Cross Pharmacy Services Provider Relations contact centre representative at

780-498-8370 (Edmonton and area)

403-294-4041 (Calgary and area)

1-800-361-9632 (toll free)

FAX 780-498-8406 (Edmonton and area)

FAX 1-877-305-9911 (toll free)

Alberta Blue Cross offers online access to current Pharmacy Benefacts and supplemental claiming information to assist with the submission of your direct bill drug claims.

Visit ab.bluecross.ca/providers/pharmacy-home.php



Carton Label (Paper box)



Parol

Acetaminophen
Acétaminophène
(120mg per 5mL)
ORAL SUSPENSION
SUSPENSION ORALE



8 6997 17 700062

Contains Acetaminophen
Contient de l'acétaminophène

For children / Pour les enfants

Parol

Acetaminophen
ORAL SUSPENSION
(120mg per 5mL)
Acetaminophene
SUSPENSION ORALE
(120mg per 5mL)

This is not a standard concentration, please see dosing table and speak with a pharmacist before use.
Ce n'est pas une concentration standard. Veuillez consulter le tableau de dosage et demander à un pharmacien avant l'utilisation.

Fever Reducer / Antipyrétique
Pain Reliever / Analgésique

Alcohol free / Sans alcool

Orange Flavor (150 ml)
Saveur d'orange

ATABAY

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
Acetaminophen 120 mg /	Pain reliever, fever reducer /
Acétaminophène 120 mg	Analgésique, antipyrétique

Uses / Usages • Reduces fever • Temporarily relieves mild to moderate aches and pains due to:
 •headache •sore throat • muscle sprains and strains
 •toothache / teething pain •common cold and flu
 •immunization / • Antipyrétique • Soulage temporairement les douleurs légères à modérées associées: •aux maux de tête •aux maux de gorge
 •aux entorses et aux foulures musculaires
 •aux maux des dents / aux douleurs de dentition
 •au rhume et à la grippe •à l'immunisation

Warnings / Mises en garde

Liver warning / Avertissement – foie

Acetaminophen may cause **severe or possibly fatal liver damage** if your child takes: •more than the recommended dose in 24 hours; •with other drugs containing acetaminophen. Symptoms of liver damage may include; yellowing of the skin/eyes, unusual tiredness, loss of appetite, dark urine, sweating, nausea, vomiting, stomach pain. / L'acétaminophène peut causer des **graves dommages au foie, possiblement mortels**, si votre enfant; •dépasse la dose recommandée par période de 24 heures •prend avec d'autres médicaments contenant de l'acétaminophène. Les symptômes des dommages au foie peuvent comprendre •jaunissement de la peau ou des yeux •urine foncée •transpiration •nausée •vomissement •maux d'estomac •fatigue inhabituelle •perte d'appétit

Allergy alert / Alerte aux allergies

Acetaminophen may cause severe skin reactions. Symptoms may include: •skin reddening •blisters •rash. **If any of the above noted symptoms occur, stop use and seek medical help right away.** / l'acétaminophène peut provoquer de graves réactions cutanées. Les symptômes peuvent inclure: •rougissement de la peau •cloques •éruption cutanée. **Si l'un des symptômes**

énumérés ci-dessus servent, cessez l'utilisation du produit et consultez un médecin immédiatement.

Do not use / Ne pas utiliser •if your child is allergic to acetaminophen or any other ingredients of this medicine, •with other drugs containing acetaminophen. If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. / •Si votre enfant a des allergies à l'acétaminophène ou à tout autre ingrédient dans ce médicament, •avec d'autres médicaments Contient de l'acétaminophène. En cas d'incertitude quant à la présence d'acétaminophène dans un médicament, renseignez-vous auprès d'un médecin ou d'un pharmacien

Ask a doctor or pharmacist before use if your child / Consultez un médecin ou un pharmacien avant l'utilisation si votre enfant

•is taking the blood thinning drug warfarin. • has liver or kidney disease / • prend un anticoagulant à base de warfarine • souffre d'une maladie du foie ou des reins

Stop use and ask a doctor if / Cessez d'utiliser et consultez un médecin si •pain lasts for more than 5 days •fever lasts more than 3 days •new symptoms occur • sore throat pain lasts for more than 2 days / •la douleur persiste plus de cinq (5) jours •la fièvre persiste après trois (3) jours •des nouveaux symptômes apparaissent * • le mal de gorge dure plus de 2 jours

● **Keep out of reach of children / Garder hors de la portée des enfants** In Case of Overdose: Call a Poison Control Center or get medical help right away. Quick medical attention is critical even if you do not notice any signs or symptoms. This package contains enough drug to seriously harm a child. / En cas de surdose: Appelez un centre antipoison ou obtenez une assistance médicale immédiate. Une attention médicale rapide est primordiale même si vous ne remarquez aucun signe ni symptôme. Ce paquet contient suffisamment de médicament pour nuire gravement à un enfant.

Directions / Mode d'emploi •Shake well before each use. •Find right dose based on chart below, if possible dose by weight. • **Do not** give more than 5 times in 24 hours. • Do not give more than directed (see liver warnings). •Single dose may be repeated every 4-6 hours, as needed. •Use only the measuring device provided. •Do not give more than directed (see liver warnings). / •bien agiter avant chaque utilisation. •trouver la bonne

dose sur la base du tableau ci-dessous, si possible la dose en fonction du poids. •**Ne pas** dépasser 5 doses par période de 24 heures • La dose unitaire peut être répétée toutes les 4 à 6 heures, au besoin. •Utiliser seulement avec le dispositif de mesure fourni. •Ne pas dépasser la dose recommandée (voir les mises en garde concernant le foie)

Weight (lb) Poids (lb)	Weight (kg) Poids (kg)	Age (yr) Âge (ans)	Dose (mL)
24-35	11-15.9	2-3	6.25
36-47	16-21.9	4-5	10
48-59	22-26.9	6-8	12.5
60-71	27-31.9	9-10	16.25
72-95	32-43.9	11	20

Other information / Autres

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

Inactive ingredients / Ingrédients inactifs

carboxymethylcellulose sodium, distilled water, glycerine, methylparahydroxybenzoate (E218), microcrystalline cellulose, orange aroma, polysorbate 80, sodium saccharine, sucrose, sunset yellow E 110 / carboxyméthylcellulose sodique, cellulose microcristalline, eau distillée, glycérine, jaune orangé E 110, méthyl parahydroxybenzoate (E218), polysorbate 80, saccharine sodique, saccharose, saveur d'orange.

Questions? 1.888.834.1871,

www.mhcaremedical.com

Manufactured by: / Fabriqué par:

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

Health Canada has permitted the importation of product approved by the Turkish Ministry of Health (#215/82) with modified packaging for the Canadian market. / Santé Canada a autorisé l'importation d'un produit approuvé par le ministère turc de la Santé (#215/82) avec un emballage modifié pour le marché canadien.

Exceptional Importation by: / Importation exceptionnelle par: MHCare Medical Suite 300, 14815 - 119 Ave, Edmonton, AB, T5L 2N9

Appendix 2: Dosing Device

