Oral Rehydration Solutions

Oral Rehydration Solutions (PDF Version - 65 KB) Oral rehydration salts generally consist of a mixture of electrolytes and glucose. When reconstituted in water to produce an oral rehydration solution (ORS), they are used for the treatment and/or prevention of mild-to-moderate dehydration caused by acute watery diarrhea. Severe dehydration constitutes a medical emergency requiring immediate intravenous rehydration, and clinical practice recommends health care practitioner supervision/monitoring in the treatment of mild-to-moderate dehydration (Buckingham 2020; Government of Canada 2015; Diggins 2008; CPS 2006; WHO 2006; WHO 2005; CDC 2003). This monograph is therefore intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for market authorizations of natural health products recommended for the prevention of mild-to-moderate dehydration caused by acute watery diarrhea. These products are not to be recommended to maintain hydration during exercise or for rehydration after exercise, as according to the World Health Organization (WHO), a clear distinction should be made between products recommended for treating and/or preventing dehydration caused by diarrhea and preparations with compositions that are designed for replacing water and salt losses during exercise (WHO 2006). Notes Text in parentheses is additional optional information which can be included on the label at the applicant's discretion. The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant on the label. Brand name: The term (re)hydration may be used provided the brand name does not imply a use beyond the approved claims. Date February 28, 2025 This monograph cannot be combined with any other monograph at Class II. Products providing any medicinal ingredients outside this monograph will require Class III assessment. Note that ingredients which contribute to body water loss, such as diuretics and diaphoretics, are not allowed in Oral rehydration solutions. Proper name(s), Common name(s), Source information Table 1. Proper name(s), Common name(s), Source information Proper name(s) Common name(s) Source ingredient(s) Sodium Sodium Sodium chloride Sodium citrate 1 Sodium citrate dihydrate Potassium Potassium Potassium chloride Potassium citrate 1 Potassium citrate, monohydrate Chloride Chloride Potassium chloride Sodium chloride Sodium chloride Sodium chloride Citric acid Potassium citrate Sodium citrate 1 Sodium citrate dihydrate D-Glucose Dextrose D-Glucose Glucose Glucose 2 Reference: NHPID 2024. 1 Anhydrous 2 Anhydrous or monohydrate. Route of administration Oral Dosage form(s) This monograph is not intended to include foods or food-like dosage forms such as ready-to-drink or powdered products if represented as beverages as per the principles outlined in the Guidance Document: Classification of products at the food-natural health product interface: products in food formats. Acceptable dosage forms are: Powder, for solution; Solution; Solution, concentrated; Tablet, for solution; Tablet, effervescent (Buckingham 2020; Diggins 2008; CPS 2006; WHO 2006; WHO 2004). Use(s) or Purpose(s) All products Helps to prevent dehydration caused by (acute/watery) diarrhea and/or vomiting (due to acute gastroenteritis) (Buckingham 2020; Government of Canada 2015; Ciccarelli et al. 2013; Diggins 2008; CPS 2006; WHO 2006; WHO 2005; Bellemare et al. 2004; Fonseca et al. 2004; WHO 2004; CDC 2003; WHO 2001; WHO-ICDDR 1994). Helps to maintain hydration status/electrolytes and fluid balance in cases of (acute/watery) diarrhea and/or vomiting (due to acute gastroenteritis) (Buckingham 2020; Government of Canada 2015; Ciccarelli et al. 2013; Diggins 2008). (Source of electrolytes and glucose to) Help(s) (to) restore/replace water/fluid and electrolytes lost in cases of (acute/watery) diarrhea and/or vomiting (due to acute gastroenteritis) (Buckingham 2020; Government of Canada 2015; Ciccarelli et al. 2013; CPS 2006; WHO 2005; CDC 2003). Products formulated as, or resulting in, the WHO formulation as outlined in Table 2 Helps to reduce duration of diarrhea, stool output, and vomiting resulting from acute watery diarrhea in children (Musekiwa and Volmink 2011; CPS 2006; Pulungsih et al. 2006; WHO 2006; WHO 2005; CHOICE Study Group 2001; Hahn et al. 2001; WHO 2001; Alam et al. 1999; Santosham et al. 1996; WHO-ICDDR 1994). Note: The terms 'Helps' or 'Helps to' can be used interchangeably on the label. Dose(s) Subpopulation(s) Infants 0-12 months; Children 1-11 years; Adolescents 12-17 years; Adults 18 years and older Quantity/Concentration All medicinal ingredients must be present in the formulation (applies to Tables 2 and 3). Osmolarity must be indicated on the PLA form under 'additional dosage information' and on the product label. Table 2. Medicinal ingredients and formulation characteristics - WHO formulation 1 Medicinal ingredients Concentration in prepared product 2 Source ingredient(s) Sodium 75 mmol/L (1.72

mg/mL or 75 mEq) Sodium chloride 3 Sodium citrate 3 Sodium citrate dihydrate Potassium 20 mmol/L (0.78 mg/mL or 20 mEq) Potassium chloride 3 Chloride 65 mmol/L (2.3 mg/mL or 65 mEq) Potassium chloride 3 Sodium chloride Citrate 10 mmol/L (1.89 mg/mL or 30 mEq) Sodium citrate 3 Sodium citrate dihydrate D-Glucose 75 mmol/L (13.5 mg/mL) Glucose 4 Total osmolarity (mOsm/L) (See Appendix 1) 245 mOsm/L 1 References: WHO 2006; WHO 2005; WHO 2004; WHO 2001; WHO-ICDDR 1994. 2 The unit 'mmol/L' should be used on the PLA form; however, the units 'mg/mL' or 'mEq' may also be used on the label. 3 Anhydrous. 4 Anhydrous or monohydrate. Table 3. Medicinal ingredients and formulation characteristics - Other acceptable formulations 1 Medicinal ingredients Concentration in prepared product 2 Source ingredient(s) Electrolytes Sodium 45 - 75 mmol/L (1.035 - 1.725 mg/mL or 45 - 75 mEq) Sodium chloride 3 Sodium citrate 3 Sodium citrate dihydrate Potassium 15 - 25 mmol/L (0.59 - 0.98 mg/mL or 15 - 25 mEq) Potassium chloride 3 Potassium citrate 3 Potassium citrate, monohydrate Chloride 25 - 80 mmol/L (0.8875 - 2.84 mg/mL or 25 - 80 mEq) Potassium chloride 3 Sodium chloride 3 Base Citrate Minimum 8 mmol/L (1.51 mg/mL or 24 mEq) Citric acid Potassium citrate 3 Sodium citrate 3 Sodium citrate dihydrate Carbohydrate D-Glucose at least 1 time the quantity of sodium in mmol/L Glucose 4 Total osmolarity (mOsm/L) (See Appendix 1) Not to exceed 280 mOsm/L (i.e. hypotonic) 1 At least one of the following references was consulted per medicinal ingredient: Buckingham 2020; Government of Canada 2015; Binder et al. 2014; Ciccarelli et al. 2013; Mathew 2009; Diggins 2008; CPS 2006; WHO 2006; WHO 2005; WHO 2004; CDC 2003; CHOICE Study Group 2001; WHO 2001; WHO-ICDDR 1994. 2 The unit 'mmol/L' should be used on the PLA form; however, the units 'mg/mL' or 'mEq' may also be used on the label. 3 Anhydrous. 4 Anhydrous or monohydrate. Direction(s) for use Infants under 12 months; Children under 2 years Give as tolerated in small amount/sips, up to 100 mL per episode of diarrhea and/or vomiting. Children 2 - 9 years Take/give as tolerated in small amount/sips, up to 200 mL per episode of diarrhea and/or vomiting. Children 10 - 11 years, Adolescents 12 - 17 years, Adults 18 years and older Take/give as tolerated in small amount/sips, up to 400 mL per episode of diarrhea and/or vomiting. Note: At least one of the following references was consulted per age group: Buckingham 2020; Government of Canada 2015; Ciccarelli et al. 2013; Diggins 2008; WHO 2006; WHO 2005; WHO 2004; CDC 2003. All products Attempt to take/give solution as soon as diarrhea begins (Government of Canada 2015; CDC 2003). Products to be dissolved/diluted (powder, for solution; solution, concentrated; tablet, for solution; tablet, effervescent) Dissolve/Dilute (e.g., 1 effervescent tablet; entire content of packet, etc.) in XX mL of potable water (Buckingham 2020; WHO 2006). If potable water is not available, use boiled water (Buckingham 2020; Government of Canada 2015). Stir the product before taking/giving (WHO 2006). Do not boil the product after it is prepared (Buckingham 2020; Government of Canada 2015). Duration(s) of use For occasional use only (Health Canada 2022). Risk information Caution(s) and warning(s) All products Get medical help right away for infants under 1 year of age as dehydration may be a medical emergency. Ask a health care practitioner/health care provider/health care professional/doctor/ physician before use if you have a gastrointestinal obstruction, cardiovascular or kidney disease (Buckingham 2020; CPS 2006; WHO 2004; CDC 2003). Ask a health care practitioner/health care provider/health care professional/doctor/ physician if diarrhea/vomiting worsen or persist for more than 24 hours (WHO 2006; WHO 2005). Ask a health care practitioner/health care provider/health care professional/doctor/ physician if diarrhea contains blood or mucus, if vomit is green or contains blood, if diarrhea/vomiting are accompanied by a high fever, yellowing of eye or skin, severe abdominal pain, or if a bowel obstruction is suspected (Buckingham 2020; Government of Canada 2015; CPS 2006; CDC 2003). Ask a health care practitioner/health care provider/health care professional/doctor/ physician if you experience irritability, confusion, tiredness/weakness, reduced urine output, dry mouth, increased heart and/or breathing rate, decreased tears and/or sunken eyes , disproportionate thirst, or swelling of the hands, face and/or feet (Diggins 2008; CPS 2006; WHO 2005; CDC 2003). Contraindication(s) Do not use for (re)hydration associated with exercise (WHO 2006; CPA 2001; IOM 1994). Known adverse reaction(s) No statement required. Non-medicinal ingredients Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database. Storage conditions Must be established in accordance with the requirements described in the Natural Health Products Regulations. Ready-to-drink products Store opened product in the refrigerator, discard remaining product after XX hours. Note: XX to be replaced with the storage time established based on stability data for the product once opened. Products to be dissolved/diluted Store reconstituted solution in the refrigerator, discard remaining solution after 24 hours (Buckingham 2020; Government of Canada 2015; WHO 2006). Specifications The finished product specifications must be established in accordance with the requirements described in the Natural and Non-Prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide The medicinal ingredient must comply with the requirements outlined in the NHPID. Osmolarity must be measured for the finished product, including non-medicinal ingredients. Example Of Product Facts: Consult the Guidance Document, Labelling of Natural Health Products for more details. References cited Alam NH, Majumder RN, Fuchs GJ, and the CHOICE Study Group. Efficacy and safety of oral rehydration solution with reduced osmolarity in adults with cholera: a randomized double-blind clinical trial. Lancet 1999;354:296-299. Bellemare

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Munos MK, Walker CLF, Black RE. The effect of oral rehydration solution and recommended home fluids on diarrhoeal mortality. International Journal of Epidemiology 2010;39: i75-i87. Wesley JW. Evaluation of Infant Rehydration Solutions. 2004. [Accessed 2024 April 11]. Available from: https://labfriendcoredataprod.blob.core.windows.net/johnmorris core-data-prod/files/micro-osmometer_1196004_13.pdf Appendix 1 Osmolarity Osmotic concentration

(osmolarity), is the measure of solute concentration, defined as the number of osmoles (Osm) of solute per litre (L) of solution (osmol/L or Osm/L). The osmolarity of a solution is usually expressed as Osm/L. Osmolarity measures the number of osmoles of solute particles per unit volume of solution. This value allows the measurement of the osmotic pressure of a solution and the determination of how the solvent will diffuse across a semipermeable membrane (osmosis) separating two solutions of different osmotic concentration. To obtain the best medical outcome, the osmolarity of the Oral Rehydration Solution should be hypotonic [less than 280 mOsm/L], and ideally in the range of [225-250 mOsm/L]. An isotonic solution [280-295 mOsm/L] will have slightly delayed absorption because there is no osmotic concentration gradient present to accelerate absorption from the intestine to the bloodstream (Wesley 2004). How to calculate Osmolarity Ionic compounds, such as salts, can dissociate in solution into their constituent ions, so there is not a one-to-one relationship between the molarity and the osmolarity of a solution. For example, sodium chloride (NaCl) dissociates into Na+ and Cl– ions. Thus, for every 1 mole of NaCl in solution, there are 2 osmoles of solute particles (i.e., a 1 mol/L NaCl solution is a 2 osmol/L NaCl solution). Both sodium and chloride ions affect the osmotic pressure of the solution. Nonionic compounds do not dissociate, and form only 1 osmole of solute per 1 mole of solute. For example, a 1 mol/L solution of glucose is 1 osmol/L. Multiple compounds may contribute to the osmolarity of a solution. For example, a 3 Osm solution might consist of: 3 moles glucose, or 1.5 moles NaCl, or 1 mole glucose + 1 mole NaCl, or 2 moles glucose + 0.5 mole NaCl, or any other such combination. For the WHO formulation which does not have any non-medicinal ingredients, osmolarity may be calculated rather than tested (addition of the concentrations of solutes, i.e. 75 + 20 + 65 + 10 + 75 = 245). If the formulation includes any non-medicinal ingredients, osmolarity may be affected so applicant must test their product to determine osmolarity. 1 mole of sodium chloride (58.44 g/mol) dissociates in 1 mole of sodium (22.98977 g/mol) and 1 mole of chloride (35.4527 g/mol). 1 mole of potassium chloride (74.55 g/mol) dissociates in 1 mole of potassium (39.0983 g/mol) and 1 mole of chloride (35.4527 g/mol). 1 mole of trisodium citrate dihydrate (294.10 g/mol) dissociates in 3 moles of sodium (22.98977 g/mol) and 1 mole of citrate (189.1 g/mol). 2.6 g of sodium chloride = 0.045 mole = 45 mmol or mOsm of sodium and 45 mmol or mOsm of chloride 1.5 g of potassium chloride = 0.020 mole = 20 mmol or mOsm of potassium and 20 mmol or mOsm of chloride 2.9 g trisodium citrate dihydrate = 0.0097 mol = 9.86 mmol or 10 mmol or mOsm of citrate and (3 x 9.86) = 29.58 mmol or mOsm of sodium 13.5 g of glucose (180.16 g/mol = 0.075 mol = 75 mmol or mOsm of glucose. 45 mmol or mOsm of sodium (from sodium chloride) + 29.58 mmol or mOsm of sodium (from trisodium citrate dihydrate) = 74.58 mmol or 75 mmol or mOsm of sodium. 45 mmol or mOsm of chloride (from sodium chloride) + 20 mmol or mOsm of chloride (from potassium chloride) = 65 mmol or mOsm of chloride Osmolarity = 20 + 10 + 75 + 75 + 65 = 245 mmol/L or mOsm/L Report a problem on this page Date modified: 2019-03-01

DOSAGE FORM(S)

Acceptable dosage forms are: Powder, for solution; Solution; Solution, concentrated; Tablet, for solution; Tablet, effervescent (Buckingham 2020; Diggins 2008; CPS 2006; WHO 2006; WHO 2004).

RISK INFORMATION

Caution(s) and warning(s) All products Get medical help right away for infants under 1 year of age as dehydration may be a medical emergency.Ask a health care practitioner/health care provider/health care professional/doctor/ physician before use if you have a gastrointestinal obstruction, cardiovascular or kidney disease (Buckingham 2020; CPS 2006; WHO 2004; CDC 2003).Ask a health care practitioner/health care provider/health care professional/doctor/ physician if diarrhea/vomiting worsen or persist for more than 24 hours (WHO 2006; WHO 2005).Ask a health care practitioner/health care provider/health care professional/doctor/ physician if diarrhea contains blood or mucus, if vomit is green or contains blood, if diarrhea/vomiting are accompanied by a high fever, yellowing of eye or skin, severe abdominal pain, or if a bowel obstruction is suspected (Buckingham 2020; Government of Canada 2015; CPS 2006; CDC 2003).Ask a health care practitioner/health care provider/health care professional/doctor/ physician if you experience irritability, confusion, tiredness/weakness, reduced urine output, dry mouth, increased heart and/or breathing rate, decreased tears and/or sunken eyes , disproportionate thirst, or swelling of the hands, face and/or feet (Diggins 2008; CPS 2006; WHO 2005; CDC 2003). Contraindication(s) Do not use for (re)hydration associated with

exercise (WHO 2006; CPA 2001; IOM 1994). Known adverse reaction(s) No statement required.

NON-MEDICINAL INGREDIENTS

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database.

STORAGE CONDITION(S)

Must be established in accordance with the requirements described in theNatural Health Products Regulations. Ready-to-drink products Store opened product in the refrigerator, discard remaining product after XX hours. Note: XX to be replaced with the storage time established based on stability data for the product once opened. Products to be dissolved/diluted Store reconstituted solution in the refrigerator, discard remaining solution after 24 hours (Buckingham 2020; Government of Canada 2015; WHO 2006).

REFERENCES

2The unit 'mmol/L' should be used on the PLA form; however, the units 'mg/mL' or 'mEq' may also be used on the label. 3Anhydrous. 4Anhydrous or monohydrate. Table 3. Medicinal ingredients and formulation characteristics - Other acceptable formulations1Medicinal ingredientsConcentration in prepared product2Source ingredient(s)ElectrolytesSodium45 - 75 mmol/L (1.035 - 1.725 mg/mL or 45 - 75 mEq)Sodium chloride3Sodium citrate3Sodium citrate dihydratePotassium15 - 25 mmol/L (0.59 - 0.98 mg/mL or 15 - 25 mEq)Potassium chloride3Potassium citrate3Potassium citrate, monohydrateChloride25 - 80 mmol/L (0.8875 - 2.84 mg/mL or 25 - 80 mEq)Potassium chloride3Sodium chloride3BaseCitrateMinimum 8 mmol/L (1.51 mg/mL or 24 mEq)Citric acidPotassium citrate3Sodium citrate3Sodium citrate dihydrateCarbohydrateD-Glucoseat least 1 time the quantity of sodium in mmol/LGlucose4Total osmolarity (mOsm/L)(See Appendix 1)Not to exceed 280 mOsm/L (i.e. hypotonic) 1At least one of the following references was consulted per medicinal ingredient: Buckingham 2020; Government of Canada 2015; Binder et al. 2014; Ciccarelli et al. 2013; Mathew 2009; Diggins 2008; CPS 2006; WHO 2006; WHO 2005; WHO 2004; CDC 2003; CHOICE Study Group 2001; WHO 2001; WHO-ICDDR 1994. 2The unit 'mmol/L' should be used on the PLA form; however, the units 'mg/mL' or 'mEq' may also be used on the label. 3Anhydrous. 4Anhydrous or monohydrate. Direction(s) for use Infants under 12 months; Children under 2 years Give as tolerated in small amount/sips, up to 100 mL per episode of diarrhea and/or vomiting. Children 2 - 9 years Take/give as tolerated in small amount/sips, up to 200 mL per episode of diarrhea and/or vomiting. Children 10 - 11 years, Adolescents 12 - 17 years, Adults 18 years and older Take/give as tolerated in small amount/sips, up to 400 mL per episode of diarrhea and/or vomiting. Note: At least one of the following references was consulted per age group: Buckingham 2020; Government of Canada 2015; Ciccarelli et al. 2013; Diggins 2008; WHO 2006; WHO 2005; WHO 2004; CDC 2003. All products Attempt to take/give solution as soon as diarrhea begins (Government of Canada 2015; CDC 2003). Products to be dissolved/diluted (powder, for solution; solution, concentrated; tablet, for solution; tablet, effervescent) Dissolve/Dilute (e.g., 1 effervescent tablet; entire content of packet, etc.) in XX mL of potable water (Buckingham 2020; WHO 2006).If potable water is not available, use boiled water (Buckingham 2020; Government of Canada 2015).Stir the product before taking/giving (WHO 2006).Do not boil the product after it is prepared (Buckingham 2020; Government of Canada 2015).

Proper name(s)	Common name(s)	Source ingredient(s)

Sodium	Sodium	Sodium chlorideSodium citrate1Sodium citrate dihydrate
Potassium	Potassium	Potassium chloridePotassium citrate1Potassium citrate, monoh
Chloride	Chloride	Potassium chlorideSodium chloride
Sodium chloride	Sodium chloride	Citric acidPotassium citrateSodium citrate1Sodium citrate dihyd
D-Glucose	DextroseD-GlucoseGlucose	Glucose2

Medicinal ingredients	Concentration in prepared product2	Source ingredient(s)
Sodium	75 mmol/L (1.72 mg/mL or 75 mEq)	Sodium chloride3Sodium citrate3Sodium citrate dihyd
Potassium	20 mmol/L (0.78 mg/mL or 20 mEq)	Potassium chloride3
Chloride	65 mmol/L (2.3 mg/mL or 65 mEq)	Potassium chloride3Sodium chloride
Citrate	10 mmol/L (1.89 mg/mL or 30 mEq)	Sodium citrate3Sodium citrate dihydrate
D-Glucose	75 mmol/L (13.5 mg/mL)	Glucose4
Total osmolarity (mOsm/L)(See Appendix 1)	245 mOsm/L	

Medicinal ingredients	Concentration in prepared product2	Source ingredient(s)
Electrolytes		
Sodium	45 - 75 mmol/L (1.035 - 1.725 mg/mL or 45 - 75 mEq)	Sodium chloride3Sodium citrate3Sodium citrate dihyd
Potassium	15 - 25 mmol/L (0.59 - 0.98 mg/mL or 15 - 25 mEq)	Potassium chloride3Potassium citrate3Potassium citr
Chloride	25 - 80 mmol/L (0.8875 - 2.84 mg/mL or 25 - 80 mEq)	Potassium chloride3Sodium chloride3
Base		
Citrate	Minimum 8 mmol/L (1.51 mg/mL or 24 mEq)	Citric acidPotassium citrate3Sodium citrate3Sodium c
Carbohydrate		
D-Glucose	at least 1 time the quantity of sodium in mmol/L	Glucose4
Total osmolarity (mOsm/L)(See Appendix 1)	Not to exceed 280 mOsm/L (i.e. hypotonic)	