

**READICAT 2.1% W/V ORAL SUSPENSION
PL 11847/0011**

UKPAR

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**READICAT 2.1% W/V ORAL SUSPENSION
PL 11847/0011**

LAY SUMMARY

The MHRA today granted E-Z-EM Limited a Marketing Authorisation (licence) for the Readicat 2.1% w/v Oral Suspension (PL 11847/0011). This is for diagnostic use by professionals as a contrast medium during Computerised Axial Tomography (CAT) scans that involve the use of X-rays. It contains barium sulphate 2.1% w/v, which coats the wall of the gastrointestinal tract and increases the absorption of X-rays as they pass through the body. This makes X-ray pictures clearer and helps doctors to diagnose any conditions.

No new or unexpected safety concerns arose from this application and it was therefore judged that the benefits of taking Readicat 2.1% w/v Oral Suspension outweigh the risks, hence a Marketing Authorisation has been granted.

**READICAT 2.1% W/V ORAL SUSPENSION
PL 11847/0011**

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the UK granted a marketing authorisation for the medicinal product ReadCat 2.1% w/v Oral Suspension (PL 11847/0011) to E-Z-EM Limited on 21st March 2007. The product is for use by professionals only.

This application for ReadCat 2.1% w/v Oral Suspension is submitted as an abridged application according to Article 10a of Directive 2001/83/EC, a bibliographic application for a new strength of an established product with recognised efficacy and an acceptable level of safety (as demonstrated by references in the product literature).

The product contains barium sulphate, a contrast medium supplied as a ready-to-use suspension for oral administration. It has been developed specifically as a gastrointestinal marker for use in Computerised Axial Tomography (CAT) scans.

Barium sulphate is an inert and radio-opaque contrast medium well-characterised in the literature. Barium sulphate has been used as a contrast medium for gastrointestinal radiography since 1911, initially for single-contrast studies and more recently in much lower concentrations for opacification of the gastrointestinal tract prior to CAT scanning.

The performance of barium sulphate preparations in producing good CAT pictures is dependent on numerous physical characteristics determined both by the particle sizes of barium sulphate and by other ingredients. Important physical characteristics include viscosity, and prevention of flocculation and foaming.

ReadCat 2.1% w/v Oral Suspension is indicated for the opacification of the gastrointestinal tract, prior to computerised axial tomography. This medicinal product is for diagnostic use only.

PHARMACEUTICAL ASSESSMENT

DRUG SUBSTANCE

Barium Sulphate

INN:	Barium sulphate
Physical form:	A white crystalline solid that is poorly soluble in water and other traditional solvents, but is soluble in concentrated sulphuric acid.
Molecular formula:	BaSO ₄
Molecular weight:	233.4
CAS number:	7727-43-7
ATC Code:	Barium sulphate with suspending agents (V08BA01)

Barium sulphate is the subject of a European Pharmacopoeia and US Pharmacopoeia monograph.

Production of the drug substance from the designated starting materials has been adequately described and appropriate in-process controls and intermediate specifications are applied. Satisfactory specification tests are in place for all starting materials and reagents and these are supported by relevant certificates of analysis.

An appropriate specification is provided for the active substance barium sulphate that is based on the European Pharmacopoeia and US Pharmacopoeia monographs. Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications.

Batch analysis data are provided and comply with the proposed specification.

No full stability studies have been submitted as the stability of the active is already well-established. A retest period of 12 months has been set, which is satisfactory.

DRUG PRODUCT

Other ingredients

Other ingredients consist of pharmaceutical excipients, namely xanthan gum, sorbitol aqueous solution 70%, simethicone emulsion 30%, sodium saccharin, sodium benzoate, potassium sorbate, benzoic acid, citric acid anhydrous, sodium citrate, banana flavour, cream flavour and water purified. All excipients used comply with their respective European Pharmacopoeia monograph, with the exception of banana flavour and cream flavour (which comply with suitable in-house specifications). Satisfactory certificates of analysis have been provided for all excipients.

None of the excipients used contain materials of animal or human origin.

Product development

The applicant has provided a suitable product development section. Justifications for the use and amounts of each excipient have been provided and are valid.

Manufacture

A description and flow-chart of the manufacturing method has been provided.

In-process controls are satisfactory based on process validation data and controls on the finished product. Process validation has been carried out on batches of finished product and the results appear satisfactory.

Finished product specification

The finished product specification is satisfactory. Test methods have been described and have been adequately validated as appropriate. Batch data have been provided and comply with the release specification. Certificates of analysis for all working standards used have been provided and are satisfactory.

Container-Closure System

The primary packaging is a high-density polyethylene bottle with a tamper-evident screw-on cap. Pack sizes are 250ml and 450ml.

Specifications and Certificates of Analysis for all packaging have been provided. These are satisfactory. The primary packaging has been shown to comply with relevant regulations regarding the contact of materials with foodstuff.

Stability

Finished product stability studies have been conducted in accordance with current guidelines. Based on the results, a shelf-life of 24 months has been set for all strengths, with the storage instructions “Avoid freezing”, “Store in original packaging” and “Do not store above 25°C”.

This product is for single-dose use only and any remaining unused suspension should be discarded after opening.

Bioequivalence

No bioequivalence studies were submitted, which is appropriate as this product was submitted under Article 10a, a bibliographic application.

ADMINISTRATIVE

Expert Report

A pharmaceutical expert report has been written by a suitably qualified person and is satisfactory.

Summary of Product Characteristics (SPC)

This is pharmaceutically satisfactory.

Labelling

These are pharmaceutically satisfactory.

Patient Information Leaflet (PIL)

This is pharmaceutically satisfactory.

The marketing authorisation holder has committed to updating the marketing authorisation license with a revised PIL and results of user testing, in accordance with Article 59 of Council Directive 2001/83/EC, no later than 1st July 2008.

MAA Form

This is pharmaceutically satisfactory.

Conclusion

It is recommended that a Marketing Authorisation is granted for this application.

PRECLINICAL ASSESSMENT

This application for Readicat 2.1% w/v Oral Suspension is submitted as an abridged application according to Article 10a of Directive 2001/83/EC, a bibliographic application for a new strength of an established product with recognised efficacy and an acceptable level of safety (as demonstrated by references in the product literature).

No new preclinical data have been supplied with this application and none are required for an application of this type.

CLINICAL ASSESSMENT

CLINICAL PHARMACOLOGY

No new data are submitted. As the product is not absorbed from the gastrointestinal tract, there is no issue of bioavailability or systemic effects. The excipients are comparable to those of other similar licensed products.

EFFICACY

No clinical studies using the product proposed for marketing are submitted. However nine references are submitted using the applicant's comparable product Polibar (also known as "E-Z-CAT"; PL 11847/0003). Summary tables of these clinical studies are provided as appendices to the clinical expert report. E-Z-CAT is one of a number of UK Marketing Authorisations currently granted for similar dilute barium sulphate formulations for use in the requested indication.

E-Z-CAT (PL 11847/0003) is licensed to the applicant. ReadiCat is supplied ready for use whilst E-Z-CAT is intended for dilution to the required strength prior to use. A range of strengths may thus be obtained, but the Summary of Product Characteristics for the product includes 2.1% w/w as a recommended strength, similar to ReadiCat (2.0% w/w).

The excipients of barium sulphate formulations, including viscosity enhancers, suspending/anti-sedimentation agents, de-foaming agents and osmotic regulators, are important determinants of performance. However, they are less critical for a dilute suspension of this type than for more concentrated suspensions intended for double contrast studies. The excipients of ReadiCat are comparable to those of E-Z-CAT diluted to 2% w/w, but are not qualitatively or quantitatively exactly the same. The applicant argues that because there are no important differences between the excipients of ReadiCat and those of E-Z-CAT diluted to 2% w/w, further clinical studies with ReadiCat are not necessary. The clinical expert states that the levels of excipient that contribute to the clinical performance of the product are very similar.

The pharmaceutical assessor has confirmed that there do not appear to be any important differences between the two products that might significantly affect the performance of the product. It, therefore, is reasonable to accept the clinical studies in the licensed product E-Z-CAT for the evidence of efficacy of ReadiCat (2.0% w/w).

SAFETY

Safety data from clinical studies of E-Z-CAT have been provided. The safety profile for E-Z-CAT and ReadiCat are expected to be the same.

EXPERT REPORTS

A clinical expert report has been written by a suitably qualified person and is satisfactory.

PATIENT INFORMATION LEAFLET (PIL)

This is consistent with that for the similar granted products and is satisfactory.

LABELLING

These are satisfactory

APPLICATION FORMS (MAA)

These are satisfactory.

SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

This is consistent with that for the similar granted products and is satisfactory.

DISCUSSION

The literature provided for this bibliographic application provides adequate evidence of the efficacy and safety of the proposed product.

MEDICAL CONCLUSION

The grant of a marketing authorisation is recommended for this application.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The important quality characteristics of ReadiCat 2.1% w/v Oral Suspension are well-defined and controlled. The specifications and batch analytical results indicate consistency from batch to batch. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

PRECLINICAL

No new preclinical data were submitted and none are required for an application of this type.

EFFICACY

The literature provided for this bibliographic application provides adequate evidence of the efficacy and safety of the proposed product.

No new or unexpected safety concerns arise from this application.

The SPC, PIL and labelling are satisfactory and consistent with that for similar products that are currently licensed.

RISK BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. Evidence of efficacy has been provided. Extensive clinical experience with barium sulphate is considered to have demonstrated the therapeutic value of the compound. The risk benefit is, therefore, considered to be positive.

**READICAT 2.1% W/V ORAL SUSPENSION
PL 11847/0011**

STEPS TAKEN FOR ASSESMENT

1	The MHRA received the marketing authorisation applications on 6 th June 2002
2	Following standard checks and communication with the applicant the MHRA considered the applications valid on 13 th August 2002
3	Following assessment of the applications, the MHRA requested further information relating to the clinical dossiers on 13 th December 2002 and 10 th November 2004, and further information relating to the quality dossiers on 13 th December 2002, 10 th November 2004 and 12 th March 2007
4	The applicant responded to the MHRA's requests, providing further information on 10 th October 2003 and 10 th September 2006 for the clinical sections, and again on 10 th October 2003, 10 th September 2006 and 16 th March 2007 for the quality sections.
5	The applications were determined on 21 st March 2007

**READICAT 2.1% W/V ORAL SUSPENSION
PL 11847/0011**

STEPS TAKEN AFTER AUTHORISATION - SUMMARY

Date submitted	Application type	Scope	Outcome

1 NAME OF THE MEDICINAL PRODUCT

ReadiCat 2.1% w/v Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION**Active ingredient:**

Barium Sulphate 2.1% w/v (2.0% w/w)

For excipients see Section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension

White suspension.

4 CLINICAL PARTICULARS**4.1 Therapeutic indications:**

This medicinal product is for diagnostic use only.

ReadiCat 2.1% w/v Oral Suspension is indicated for the opacification of the gastro-intestinal tract, prior to computerised axial tomography.

4.2 Posology and method of administration

For oral administration.

The dose administered will be dependent upon the patient and technique involved and will be determined, from experience, by the radiologist.

Adults: Suggested 30 minute Barium Administration Protocol for Abdomen studies : 300 ml of contrast to be administered 30 minutes prior to the scan and 150 ml immediately before the scan.

Suggested 90 minute Barium Administration Protocol for Abdomen/Pelvis studies : 450 ml of contrast to be administered 90 minutes prior to the scan, another 300 ml 30 minutes before the scan, and finally 150 ml immediately before the scan.

Children: The quantity of ReadiCat 2.1% w/v Oral Suspension should be determined, from experience, by the physician and will be dependent on the age and weight of the child.

4.3 Contraindications

ReadiCat 2.1% w/v Oral Suspension should not be used if the patient has hypersensitivity to barium sulphate or any of the excipients in ReadiCat 2.1% w/v Oral Suspension. Patients with actual or suspected gastro-intestinal perforation or intestinal obstruction should not be given ReadiCat 2.1% w/v Oral Suspension.

4.4 Special warnings and precautions for use

ReadiCat 2.1% w/v Oral Suspension should be used under medical supervision and should be used with caution in patients who are severely debilitated or have severe hypertension or advanced cardiac disease. Ingestion of this product is not recommended in patients with a history of food aspiration. If barium studies are required in these patients or in patients in whom integrity of the swallowing mechanism may be compromised, proceed with caution. If this product is aspirated into the larynx further administration should be immediately discontinued.

There is no evidence that 2.1% w/v barium sulphate suspensions give rise to acute peritonitis, as seen with high concentration (>40% w/v) suspensions, therefore ReadiCat 2.1% w/v Oral Suspension should be used with caution in patients with known or suspected perforation of the gastro-intestinal tract.

After any barium study of the gastro-intestinal tract, it is important to rehydrate the patient as quickly as possible.

4.5 Interaction with other medicinal products and other forms of interaction

The presence of barium sulphate formulations in the gastro-intestinal tract may alter the absorption of therapeutic agents taken concomitantly. In order to minimise any potential change in absorption, the separate administration of barium sulphate from that of other agents should be considered.

4.6 Pregnancy and lactation

In principle there are no objections against barium sulphate during pregnancy. Since radiation exposure during pregnancy should be avoided anyway, regardless whether a contrast agent is used or not, the benefit of X-ray examination has to be considered carefully.

4.7 Effects on ability to drive and use machines

As far as it is known, Readicat 2.1% w/v Oral Suspension has no influence on the ability to drive and use machines

4.8 Undesirable effects

Undesirable effects such as nausea, vomiting, diarrhoea and abdominal cramping, accompanying the use of barium sulphate are infrequent and usually mild.

Procedural complications are rare, but may include aspiration pneumonitis, granuloma formation, intravasation, embolisation and peritonitis following intestinal perforation.

Due to the increased likelihood of allergic reactions in atopic patients, it is important that a complete history of known and suspected allergies, as well as allergic symptoms such as rhinitis, bronchial asthma, eczema and urticaria, is obtained prior to any medical procedure using this product. A mild allergic reaction would most likely include such symptoms as generalised pruritis, erythema or urticaria [approximately 1 in 250,000]. Very rarely, more serious reactions [approximately 1 in 1,000,000] such as laryngeal oedema, bronchospasm or hypotension could develop.

4.9 Overdose

No case of overdose has been reported.

Barium sulphate is non-toxic.

5 PHARMACOLOGICAL PROPERTIES**5.1 Pharmacodynamic properties**

Pharmacotherapeutic Group: X-ray Contrast Media, Barium Sulphate
ATC code: V08BA01

Barium sulphate itself has no pharmacological effects. Its use is based on the absorption of X-rays during visualisation of the gastro-intestinal tract.

5.2 Pharmacokinetic properties

Not applicable. Barium sulphate, the active constituent of Readicat 2.1% w/v Oral Suspension is not absorbed from the gastro-intestinal tract.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included elsewhere in the SmPC.

6 PHARMACEUTICAL PARTICULARS**6.1 List of excipients**

Sorbitol, liquid (non-crystallising) (E420)
Xanthan Gum (E415)
Simethicone Emulsion 30%
Artificial Cream Flavour [including maltodextrin, propylene glycol and artificial flavours]
Potassium Sorbate (E202)
Natural Banana Flavour [including maltodextrin, natural flavours and ethanol]
Benzoic Acid (E210)

Sodium Benzoate (E211)
Sodium Saccharin (E954)
Sodium Citrate (E331)
Anhydrous Citric Acid (E330)
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Shelf life as packaged for sale

Two years.

Shelf Life after first opening of the container

For single dose use only. Discard any unused suspension immediately after initial use.

6.4 Special precautions for storage

Do not store above 25°C. Store in original packaging. Do not freeze.

6.5 Nature and contents of container

ReadiCat 2.1% w/v Oral Suspension is supplied in high density polyethylene (HDPE) bottles with polypropylene screw cap and tamper evident neck seal. Bottles containing either 250 ml or 450 ml of product are available.

6.6 Special precautions for disposal

Do not accept if the tamper-evident seal is broken. For single dose use only. Discard any unused suspension immediately after initial use.

7 MARKETING AUTHORISATION HOLDER

E-Z-EM Limited,
Avonbury Business Park,
Howes Lane,
Bicester,
Oxfordshire,
OX26 2UB,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

PL 11847/0011

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21/03/2007

10 DATE OF REVISION OF THE TEXT

21/03/2007

READICAT™ 2.1% w/v ORAL SUSPENSION

(BARIUM SULPHATE)



Please read this leaflet carefully. It contains important information about a product called ReadiCat 2.1% w/v Oral Suspension which you will be asked to take before your X-ray procedure.



WHAT IS READICAT 2.1% w/v ORAL SUSPENSION?

ReadiCat 2.1% w/v Oral Suspension is a white oral suspension which contains the active ingredient barium sulphate 2.1% w/v (2.0% w/w). This product also contains sorbitol, liquid (non-crystallising).

In addition, ReadiCat 2.1% w/v Oral Suspension also contains: xanthan gum (E415), simethicone emulsion 30%, artificial cream flavour [including maltodextrin, propylene glycol and artificial flavours], potassium sorbate (E202), natural banana flavour [including maltodextrin, natural flavours and ethanol], benzoic acid (E210), sodium benzoate (E211), sodium saccharin (E954), sodium citrate (E331), anhydrous citric acid (E330) and purified water.

ReadiCat 2.1% w/v Oral Suspension is supplied in plastic bottles fitted with tamper-evident closures, containing either 250 ml or 450 ml of product. Cartons containing 24 bottles are available.

WHAT IS READICAT 2.1% w/v ORAL SUSPENSION USED FOR?

This medicinal product is for diagnostic use only.

ReadiCat 2.1% w/v Oral Suspension is a contrast medium used during CT (or CAT) scans, which involve the use of X-rays. It acts by coating the wall of your gastro-intestinal tract and increasing the absorption of X-rays as they pass through the body. This makes the X-ray 'pictures' clearer which helps your doctor to diagnose your condition.

Marketing Authorisation Holder:
E-Z-EM Limited, Bicester, OX26 2UB, UK.

Manufacturer responsible for batch release in the EU:
E-Z-EM Limited, Bicester, OX26 2UB, UK.

WHEN SHOULD READICAT 2.1% w/v ORAL SUSPENSION NOT BE USED?

Before you take the product, you should tell your doctor if you are taking any other medication and also if you are pregnant or think you could be pregnant. Although ReadiCat 2.1% w/v Oral Suspension is unlikely to harm your baby, there is a possibility that exposure to X-rays might do so. It is safe for ReadiCat 2.1% w/v Oral Suspension to be given to you if you are breast-feeding.

ReadiCat 2.1% w/v Oral Suspension should not be given to you if you are hypersensitive to barium sulphate or any other ingredients in this product.

Please tell your doctor if you have high blood pressure or heart problems, or if you have swallowing difficulties.

Your doctor will determine if ReadiCat 2.1% w/v Oral Suspension should not be given to you.

If you have a known or suspected perforation of the gastro-intestinal tract, or intestinal obstruction, you should not be given ReadiCat 2.1% w/v Oral Suspension.

This product contains sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. The calorific value of sorbitol is 2.6 kcal/g. Each 100ml of ReadiCat 2.1 % w/v Oral Suspension contains 2.67g

of sorbitol. When taken according to the dosage recommendation for abdomen studies, each dose will supply 12g of sorbitol and for abdomen/pelvis studies each dose will supply 24g of sorbitol.

Each 100ml of ReadiCat 2.1%w/v Oral Suspension contains 72mg of potassium. This should be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

Each 100ml of ReadiCat 2.1%w/v Oral Suspension contains 16mg of sodium. This should be taken into consideration by patients on a controlled sodium diet.

Please tell your doctor if any of these circumstances apply to you.

ReadiCat 2.1% w/v Oral Suspension contains a small quantity of ethanol (alcohol), less than 100mg per 100ml.

HOW IS READICAT 2.1% w/v ORAL SUSPENSION ADMINISTERED?

For oral administration only.

Depending on the area of the body under investigation, you may be asked to drink a quantity (450 ml) of ReadiCat 2.1% w/v Oral Suspension 90 minutes before your scan. In all investigations, you will be asked to drink a quantity (300 ml) of ReadiCat 2.1%w/v Oral Suspension 30 minutes before your scan and then another quantity (150 ml) immediately before your scan.

Ensure that you drink the entire quantity you are given.

Ask your doctor if you would like an explanation of how the scan is conducted.

You should drink plenty of water following your investigation.

Shake well before use.

WHAT UNDESIRABLE EFFECTS MAY READICAT 2.1% w/v ORAL SUSPENSION CAUSE?

Some patients find that they experience stomach cramps, nausea, vomiting, or diarrhoea. Effects like these normally only occur for a short period after the procedure and are not considered serious.

Procedures involving ReadiCat 2.1%w/v Oral Suspension are extremely safe and most people will not experience any undesirable effects afterwards, however, as with all medical procedures, there is a very small risk that side-effects or complications can occur. Rarely, the procedure may lead to damage to the lining or the wall of the intestine. If this happens, an infection of the intestine or lining of the abdominal cavity (peritonitis) can result.

Very occasionally, small amounts of the barium sulphate can get into the blood supply and be distributed to other parts of the body such as veins and arteries. There is also a small risk that some of the barium sulphate will be inhaled into the lungs. This can lead to inflammation and infection of the lungs.

This product contains sorbitol, which may have a mild laxative effect in some patients.

Rarely, an allergic reaction to one of the constituents of ReadiCat 2.1% w/v Oral Suspension has been reported.

It is important to remember that the side-effects listed above only happen rarely. However, if you feel unwell or have any unusual discomfort or pain, tell your doctor or pharmacist.

It is also important to follow any directions given to you by your doctor or radiographer once the examination is completed.

HOW TO STORE READICAT 2.1% w/v ORAL SUSPENSION

Store in the original packaging. Do not store above 25°C. Do not freeze. Do not accept if tamper evident seal is broken. For single dose use only. Discard any unused suspension immediately after initial use. Each bottle carries an expiry date after which the product must not be used.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

Date of last revision of leaflet: June 2006


Active ingredient: Barium Sulphate 2.1% w/v (2.0% w/w) **Other constituents:** Sorbitol, liquid (non-crystallising) (E420) (see leaflet for further information), xanthan gum (E415), simethicone emulsion 30%, artificial cream flavour [including maltodextrin, propylene glycol and artificial flavours], potassium sorbate (E202), natural banana flavour [including maltodextrin, natural flavours and ethanol (see leaflet for further information)], benzoic acid (E210), sodium benzoate (E211), sodium saccharin (E954), sodium citrate (E331), anhydrous citric acid (E330), purified water. Contains potassium and sodium. Each 250 ml of Readicat 2.1% w/v Oral Suspension contains approximately 40mg sodium and 7g sorbitol, liquid (non-crystallising). **Indications:** An oral contrast medium for the opacification of the gastro-intestinal tract prior to computerised axial tomography. **Contra-indications:** Readicat 2.1% w/v Oral Suspension should not be used if the patient has hypersensitivity to barium sulphate or any of the constituents in Readicat 2.1% w/v Oral Suspension. Patients with actual or suspected gastro-intestinal perforation or intestinal obstruction, should not be given Readicat 2.1% w/v Oral Suspension.

CT STUDIES

**READICAT™ 2.1% w/v
ORAL SUSPENSION**

Barium Sulphate
**This medicinal product
is for diagnostic use only**

250 ml
Shake well before use



EZEM®
MARKETING
AUTHORISATION HOLDER:
E-Z-EM Limited
Bicester, OX26 2UB, UK
PL 11847/0011

Dosage and administration: Readicat 2.1 %w/v Oral Suspension is for oral administration. The dose administered will be dependent upon the patient and technique involved and will be determined, from experience, by the radiologist. **Adults:** Suggested 30 minute Barium Administration Protocol for Abdomen studies: Administer 300 ml of contrast 30 minutes prior to the scan and 150 ml immediately before the scan. Suggested 90 minute Barium Administration Protocol for Abdomen/Pelvis studies: Administer 450 ml of contrast 90 minutes prior to the scan, another 300 ml 30 minutes before the scan, and finally 150 ml immediately before the scan. **Children:** The quantity of Readicat 2.1 % w/v Oral Suspension should be determined, from experience, by the physician and will be dependent on the age and weight of the child. **Storage:** Store in the original packaging. Do not store above 25°C. Do not freeze. Do not accept if the tamper evident seal is broken. For single dose use only. Discard any unused suspension immediately after initial use. **KEEP OUT OF THE REACH AND SIGHT OF CHILDREN** P

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Active ingredient: Barium Sulphate 2.1% w/v (2.0% w/w). **Other constituents:** Sorbitol, liquid (non-crystallising) (E420) (see leaflet for further information), xanthan gum (E415), simethicone emulsion 30%, artificial cream flavour [including maltodextrin, propylene glycol and artificial flavours], potassium sorbate (E202), natural banana flavour [including maltodextrin, natural flavours and ethanol (see leaflet for further information)], benzoic acid (E210), sodium benzoate (E211), sodium saccharin (E954), sodium citrate (E331), anhydrous citric acid (E330), purified water. Contains potassium and sodium. Each 450 ml of ReadiCat 2.1% w/v Oral Suspension contains approximately 72mg sodium and 12g sorbitol, liquid (non-crystallising). **Indications:** An oral contrast medium for the opacification of the gastro-intestinal tract prior to computerised axial tomography.

Contra-indications: ReadiCat 2.1% w/v Oral Suspension should not be used if the patient has hypersensitivity to barium sulphate or any of the constituents in ReadiCat 2.1% w/v Oral Suspension. Patients with actual or suspected gastro-intestinal perforation or intestinal obstruction, should not be given ReadiCat 2.1% w/v Oral Suspension.

CT STUDIES

READICAT™ 2.1%w/v ORAL SUSPENSION

Barium Sulphate

This medicinal product is for diagnostic use only

Shake well before use

450 ml



MARKETING AUTHORISATION HOLDER:
E-Z-EM Limited,
Bicester, OX26 2UB, UK

PL 11847/0011

Dosage and administration: ReadiCat 2.1% w/v Oral Suspension is for oral administration. The dose administered will be dependent upon the patient and technique involved and will be determined, from experience, by the radiologist.

Adults: Suggested 30 minute Barium Administration Protocol for Abdomen studies: Administer 300 ml of contrast 30 minutes prior to the scan and 150 ml immediately before the scan. Suggested 90 minute Barium Administration Protocol for Abdomen/Pelvis studies: Administer 450 ml of contrast 90 minutes prior to the scan, another 300 ml 30 minutes before the scan, and finally 150 ml immediately before the scan. **Children:** The quantity of ReadiCat 2.1% w/v Oral Suspension should be determined, from experience, by the physician and will be dependent on the age and weight of the child.

Storage: Store in the original packaging. Do not store above 25°C. Do not freeze. Do not accept if the tamper evident seal is broken. For single dose use only. Discard any unused suspension immediately after initial use.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

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