SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Phybag 9 mg/ml, solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains 9 mg sodium chloride.
100 ml contains 15.4 mmol (equivalent to 354 mg) of sodium.
150 ml contains 23.1 mmol (equivalent to 531 mg) of sodium.
200 ml contains 30.8 mmol (equivalent to 708 mg) of sodium.
500 ml contains 77 mmol (equivalent to 1770 mg) of sodium.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
Clear, colourless solution.
pH: 4.5 – 7.0
Osmolarity: 289 mOsm/l

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

This medicinal product is for diagnostic use only.
Phybag is indicated for use in adults in flushing compatible contrast agents through intravenous administration sets into indwelling intravenous access devices when delivered by power injectors.

4.2 Posology and method of administration

Posology
The volume and injection rate of Phybag flush needs to be determined for each patient individually based on:

- the imaging protocol
- the location of the intravenous access device, the length of tubing between the soft bag and the patient
- and the body weight, fluid status and concomitant medical conditions of the patient.

Phybag flush volume following contrast agent administration is usually 20 to 50 ml per injection at a rate of 3 to 5 ml/sec and should normally not exceed 100 ml. Injection rate should not exceed 10 ml/sec.

Elderly
No dosage adjustment is considered necessary. Caution should be exercised in administration to elderly patients (see section 4.4).

Paediatric Population
The safety and efficacy of Phybag administered by power injector in pediatric patients have not been established.
Administration of Phybag by power injector to pediatric patients is not recommended.

Method of administration
Intravenous use delivered by an appropriate power injector.

Use aseptic techniques.
Remove the overpouch.
Remove the cap and connect the bag to the injection line.
To contain the risk of contamination, connect each Phybag once only.
Break the seal (breakable luer) to establish the liquid flow.
Proceed with the injection.

Discard any unused product at the end of the examination session.

4.3 Contraindications

None.

4.4 Special warnings and precautions for use

Fluid overload
Sodium chloride may cause fluid overload in patients with congestive heart failure, severe renal insufficiency, and in clinical states with edema, sodium retention, or hypernatremia. In the at risk patients the sodium chloride volume should be adjusted to the clinical cardiovascular and fluid status.
Consider each patient's age, body weight, fluid status, concomitant medical conditions and planned radiological procedure to determine if use of sodium chloride is appropriate. Care should be taken when used in elderly patients, in patients with known cardiac or renal disease, as well as in conditions which may give rise to spurious hyponatremia such as pseudohyponatremia.

Air Embolism
Remove all air from the injection devices prior to injection, to avoid air embolism and related complications (risk of stroke, organ ischemia and/or infarction, and death).

Infectious complications

Use of damaged soft bag or failure to maintain aseptic technique may result in infection, sepsis and death (see section 6.6).

Extravasation
Extravasation of sodium chloride may cause mechanical compression of neurovascular structures.
Establish intravascular catheter patency prior to the administration of sodium chloride.

Paediatric Population
The safety and efficacy of Phybag administered by power injector in pediatric patients have not been established.
Administration of Phybag by power injection to pediatric patients is not recommended.

Elderly
In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug.

For dose up to 6.5 ml
This medicinal product contains less than 1 mmol sodium (23 mg), i.e. it is essentially "sodium-free".

For doses of more than 6.5 ml
To be taken into consideration for patients on a controlled sodium diet.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy and Breast-feeding
As some imaging procedures (e.g. involving X-ray) and some contrast agents are not recommended during pregnancy and lactation, it is preferable to avoid use of Phybag during pregnancy and lactation.
Fertility
No data available, however no effects are anticipated.

4.7 Effects on ability to drive and use machines

Phybag has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The adverse reactions are listed in the table below by SOC (System Organ Class) and by frequency with the following guidelines: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10 000

to <1/1 000), very rare (<1/10 000), not known (cannot be estimated from the available data).

System Organ Class	Frequency: adverse reaction
Infections and infestations	Not known: infection (sepsis)
Metabolism and nutrition disorders	Not known: fluid overload
Vascular disorders	Not known: air embolism, venous thrombosis
Gastrointestinal disorders	Not known: nausea, vomiting, diarrhoea
General disorders and administration site conditions	Not known: extravasation, injection site infection, injection site thrombosis, injection site phlebitis, pyrexia

These adverse reactions may be associated with the technique of administration.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Overdosage of sodium chloride may cause electrolyte disturbance and/or fluid overload, particularly in patients with compromised renal or cardiac function. General undesirable effects of an excess of sodium include nausea, vomiting, diarrhea. Excess chloride in the body may cause a loss of bicarbonate, with an acidifying effect.

In the event of overdose, reevaluate the patient and institute appropriate corrective action to remove sodium excess of water. The basic aim of therapy is to restore the volume and composition of the body fluids to normal.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Solvents and diluting agents, including irrigating solutions. ATC code: V07AB.

Sodium is the primary cation of the extracellular space and together with various anions, regulates its volume. Sodium and potassium are the major mediators of bioelectric processes within the body. The sodium content and the fluid status of the body are closely coupled to each other. Each deviation of the plasma sodium concentration from the physiological one simultaneously

affects the fluid status of the body. An increase in the sodium content of the body also means reduction of the body's free water content independent of the serum osmolality

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

The safety of sodium chloride in animals is not relevant in view of its presence as a normal component in animal and human plasma.
The safety data of additive should be considered separately.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injection
Sodium hydroxide (for pH adjustment, if needed)
Hydrochloric acid (for pH adjustment, if needed)

6.2 Incompatibilities

Phybag is intended to be used in flushing contrast agents.
In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

3 years.
From a microbiological point of view, unless the method of opening precludes the risk of microbial contamination, the product should be used immediately.
If not used immediately, in-use storage times and conditions are the responsibility of the user.

6.4 Special precautions for storage

Do not freeze.

6.5 Nature and contents of container

Polypropylene bags: 100, 150, 200 and 500 ml.
Phybag is available in presentation of 1 or 10 bags.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Prior to use, inspect the overpouch and the soft bag for signs of damages or leakages.
Do not use if any of them shows any signs of damages or leakages.
Do not use if the solution is not clear and colorless or contains particulate matter.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Guerbet
BP 57400
95943 Roissy CdG Cedex
France

8 MARKETING AUTHORISATION NUMBER(S)

PL 12308/0026

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

15/01/2016

10 DATE OF REVISION OF THE TEXT

15/01/2016