



Fidson Healthcare Plc

**PACKAGING SPECIFICATION SHEET (PSS)
FHP/SOP/BDS/008/03/F02**

Attachment 2

Title:	Packaging Specification Sheet for Forste Suspension			Page 1 of 1	
File No:	FHP/BD/001	Packaging tracking code:	PMN0945-1123-01	Doc code:	PIL078-1123-01

Product Name:	Forste Suspension	Artwork Type:	Insert Leaflet
Type of Paper	White Bond Paper (50gsm)	Dimension:	L-150mm; H-250mm
Finishing:	n/a	Colour Profile:	Pantone
Design type:	Vector (CDR)		Black
Fold type:	n/a		
Revision History:	n/a	Version:	01

150.00 mm

250.00 mm

FORSTE[®]

Azithromycin 200mg/5ml

Azithromycin for Oral Suspension

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Read this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or healthcare provider. This includes any possible side effects not listed in this leaflet.

In this leaflet:

1. What Forste Suspension is and what it is used for
2. What you need to know before you are given Forste Suspension
3. How to use Forste Suspension
4. Possible side effects
5. How to store Forste Suspension
6. Contents of the pack and other information

1. WHAT FORSTE SUSPENSION IS AND WHAT IT IS USED FOR
Forste Suspension belongs to a group of antibiotics called macrolides. It is used to treat infections caused by certain bacteria and other microorganisms; some examples of these infections are listed below:

- Chest, throat, and nasal infections (inflammation of bronchi, lungs and sinuses etc.)
- Infections of tonsils caused by *Streptococcus pyogenes* (tonsillitis), in treatment of sore throat (pharyngitis) in presence of Penicillin allergy
- Acute ear infections (acute otitis media)
- Skin and soft tissue infections (abscesses or boils etc.)
- Sexually transmitted diseases caused by a microorganism called Chlamydia
- Soft tissue ulcers caused by a microorganism called Haemophilus ducreyi and uncomplicated genital infections caused by a non-multi-resistant microorganism called Neisseria gonorrhoeae, when there are no other accompanying infections.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE GIVEN FORSTE SUSPENSION
Do not use Forste Suspension:

- If you are allergic to Azithromycin or any other macrolide antibiotic such as Erythromycin or Clarithromycin or any of the ingredients in FORSTE Suspension. An allergic reaction may cause skin rash or wheezing.
- If you have liver problems.
- If you are using any ergot derivatives such as Ergotamine (used to treat migraine).

Take special care with FORSTE SUSPENSION

- If you have kidney problems.
- If you have heart disease.
- If there is a community-acquired infection
- If you have been diagnosed or suspected that bacteria or bacterial toxins are present in blood.
- If you are bedridden.
- If you are old or very weak.
- If you have other serious health problems (immunodeficiency or absence of a spleen at birth; spleen was removed by surgery (splenectomy), etc.)
- If you have a liver disease.
- As with other antibiotics, there is risk of a secondary infection caused by non-susceptible organisms including fungi when your body has already been weakened by an existing infection, therefore you should be monitored by your doctor against this risk.
- If you develop diarrhea.

Please consult your doctor, even if these warnings were applicable to you at any time in the past.

Using FORSTE SUSPENSION with food and drink
FORSTE SUSPENSION is not affected by food or drink.

Pregnancy
Consult your doctor or pharmacist before taking this medicine. If you

are pregnant or planning to get pregnant, you should consult your doctor before taking FORSTE suspension.

FORSTE suspension should not be used during pregnancy unless it is clearly needed.
If you realize that you are pregnant during therapy, consult your doctor or pharmacist immediately.

Breast-feeding
Consult your doctor or pharmacist before taking this medicine. It is not known whether FORSTE suspension is excreted in human milk. You should not take FORSTE suspension without discussing it with your doctor first.

Driving and using machines
FORSTE suspension is not expected to affect your ability to drive or use machines.

Important information about some of the ingredients of FORSTE suspension
This medicine contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking FORSTE suspension. This medicine contains than 1.2 mmol Sodium (27.56 mg), to be taken into consideration by patients on a controlled Sodium diet.

Using other medicines
Tell your doctor before taking FORSTE suspension, if you are taking any of the medicines listed below and consult your doctor or pharmacist if you have any further questions about FORSTE suspension and other drugs:

- Ergot or Ergotamine
- Warfarin or any similar medicine to prevent blood clots
- Cyclosporine (used to suppress the immune system to prevent and treat rejection of a transplanted organ or bone marrow)
- Digoxin (used to treat heart failure)
- Theophylline (used to treat asthma)
- Nelfinavir (used to treat HIV infection)

If you are using antacids for indigestion, you should take FORSTE suspension one hour before or two hours after taking antacids.

Low number of neutrophils was observed in subjects receiving concomitant treatment of FORSTE suspension and Rifabutin.

If you are taking or have recently taken any other medicines, including medicines obtained without prescription, please tell your doctor or pharmacist.

3. HOW TO USE FORSTE SUSPENSION
Instructions for proper use and dose/frequency of administration:

FORSTE suspension is generally used for children under 45 kg. It may also be used in adults and older children who have difficulty swallowing capsules.

FORSTE suspension should be taken as a single daily dose.

The dosage for treatment of sexually transmitted diseases due to Chlamydia trachomatis, Haemophilus ducreyi or susceptible Neisseria gonorrhoeae is 1000 mg as a single oral dose.

The dosage for treatment of tonsillitis/pharyngitis due to S. pyogenes, is 500 mg on day 1 and 250 mg daily on days 2 through 5, the duration of therapy is 5 days.

For all other indications, total dosage is 1500 mg, taken as 500 mg daily for 3 days.

For pediatric patients weighing over 45 kg, adult doses are administered.

The usual dose in children less than 45 kg is 10 mg/kg of bodyweight, given as a single daily dose for 3 days.

Except for the treatment of Streptococcal pharyngitis, in children, total dose of 30 mg/kg given as 10 mg/kg once daily for 3 days or 10 mg/kg as a single dose on the first day followed by 5 mg/kg/day on days 2-5.

As alternative to the above dosing, 30 mg/kg may be given as a single dose for the treatment of acute ear infections (acute otitis media).

For pediatric Streptococcal pharyngitis, Azithromycin was effective as a single daily dose of 10 mg/kg or 20 mg/kg for 3 days, but daily doses of 500 mg should not be exceeded.

Your doctor may prescribe different doses to the above stated.

Method and route of administration
Taken by mouth.

Reconstitution
Shake the dry powder in bottle. Afterwards, pour boiled and then cooled water up to the mark on the supplied measuring device, add into the contents of bottle and shake well. 5 ml of the reconstituted suspension contains 200 mg of Azithromycin. Shake the bottle before each use.

Use in children.
Information regarding the use of FORSTE suspension in children is given above.

Its use is not recommended for infants younger than 6 months of age.

Use in elderly
The same dosage as in adult patients is used in elderly patients.

Special conditions
Kidney failure:
No dosage adjustment is recommended in mild to moderate kidney failure. Caution should be exercised when Azithromycin is administered in severe kidney failure.

Liver failure
Same doses may be administered in mild to moderate liver failure as with normal liver function. It should not be used in case of severe liver failure.

If you have the impression that the effect of FORSTE is too strong or too weak, talk to your doctor or pharmacist.

If you take more FORSTE suspension than you should
If you take more FORSTE suspension than you should, you may feel unwell. In such a case, tell your doctor or contact the nearest hospital emergency department immediately. Take the remaining medicine with you.

If you think you have taken more FORSTE suspension than you should, consult your doctor or pharmacist.

If you forget to take FORSTE suspension
If you forget to take FORSTE suspension, take it as soon as you can. Take your next dose at the right time.
Do not take a double dose to make up for a forgotten dose.

If you stop taking FORSTE suspension
If you stop taking FORSTE suspension too soon, the infection may return.
Take FORSTE suspension for the full time of treatment recommended by your doctor, even when you begin to feel better. Do not stop using FORSTE suspension without consulting your doctor.

If you have any further questions about the use of this product, ask your doctor or pharmacist for advice.

Possible side effects
Like all medicines, FORSTE suspension may cause side effects in people sensitive to ingredients.
Tell your doctor immediately if you experience any of the following symptoms after taking this medicine. Although they are very rare, the symptoms can be severe:

- Irregular heartbeat, shortness of breath, dizziness or fainting while using FORSTE suspension.
- Sudden wheezing
- Difficulty breathing
- Swelling of eyelids
- Swelling of face or lips
- Rash or itching (especially affecting the whole body).

The most common side effects that occur when taking FORSTE suspension are listed below. These may go away during treatment as your body adjusts to the medicine. Tell your doctor if any of these side effects continue to bother you.

Side effects are classified in the following frequencies:
Very common: affects at least 1 in 10 patients
Common: affects 1 to 10 patients in 100
Rare: affects 1 to 10 patients in 10,000
Very rare: affects less than 1 patient in 10,000
Unknown: cannot be estimated from the available data.

- Very common
 - Diarrhea
 - Stomach cramps
 - Feeling sick
- Flatulence

Common

- Headache, drowsiness
- Tired and restless or numbness
- Taste disturbance, loss of appetite
- Visual disturbances, dizziness
- Being sick, indigestion
- Rash, itching
- Joint pain
- Low number of lymphocytes (type of white blood cells), higher number of eosinophils (type of white blood cell) counts
- Low blood bicarbonate
- Tiredness

Uncommon

- Head infections of the mouth and vagina (thrush)
- Low number of leucocytes (type of white blood cells) and low number of neutrophils (type of white blood cells)
- Allergic reactions various severity
- Widespread skin rash and blistering of the skin
- Severe skin reactions due to exposure to light or sunlight
- Hives
- Feeling nervous
- Reduced sense of touch
- Sleepiness
- Sleeplessness
- Poor hearing or ringing in the ears (irreversible)
- Irregular heartbeat
- Constipation
- Inflammation of the liver
- Chest pain
- General loss of strength
- Swelling
- General discomfort
- Abnormal laboratory test values (e.g. blood or liver tests)
- Vomiting associated with abdominal pain (which may be bloody)

Rare

- Agitation
- Dizziness (vertigo)
- Abnormal liver functions

Other side effects in post-marketing experience

Unknown

- Aggression, anxiety, fits, hyperactivity, fainting
- Loss of smell or altered sense of smell, loss of taste
- Disorder of heart rhythm, fast heartbeat, irregular heart beat
- Low blood pressure
- Inflammation of the pancreas, tongue discoloration, severe skin reactions
- Liver failure, liver dysfunction, jaundice, skin redness
- Kidney failure, inflammation of kidney
- Abnormal electrocardiogram (ECG)
- Stomach pain associated with diarrhea and fever
- Easily bruising or bleeding
- Tiredness associated with dark urine.
- Local muscle weakness

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

4. HOW TO STORE FORSTE SUSPENSION
• Keep all medicines out of the reach of children.
• Store below 20°C, in a dry place.
• Do not use this medicine after the expiry date 'Exp. Date' which is stated on the label and inner carton. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

5. FURTHER INFORMATION
What Forste Suspension contains
Each 5ml of Forste Suspension contains 200mg of Azithromycin.

What Forste Suspension looks like and contents of the pack
30ml power for suspension placed in an inner carton with insert.

Manufactured by:
Fidson Healthcare Plc.,
17-21, Fidson Avenue,
Sango-Oja, Ogun State, Nigeria
234-9087703988
customerscare@fidson.com

PMN0945-1123-01

THE ARTWORK HERE IS FOR SPECIFICATION EVALUATION PURPOSES ONLY. PLEASE DO NOT USE THE ARTWORK IN THIS PSS FOR PROOF OR FINAL PRINT.

	Prepared By:	Authorized by:	Authorized by:	Approved by:
Signature				
Date	08-02-2024	08-02-2024	12-02-2024	17-02-2024
Designation	GA	GM-BD&S	HoM	GM-Q & RA
				19 February 2024
				C.D