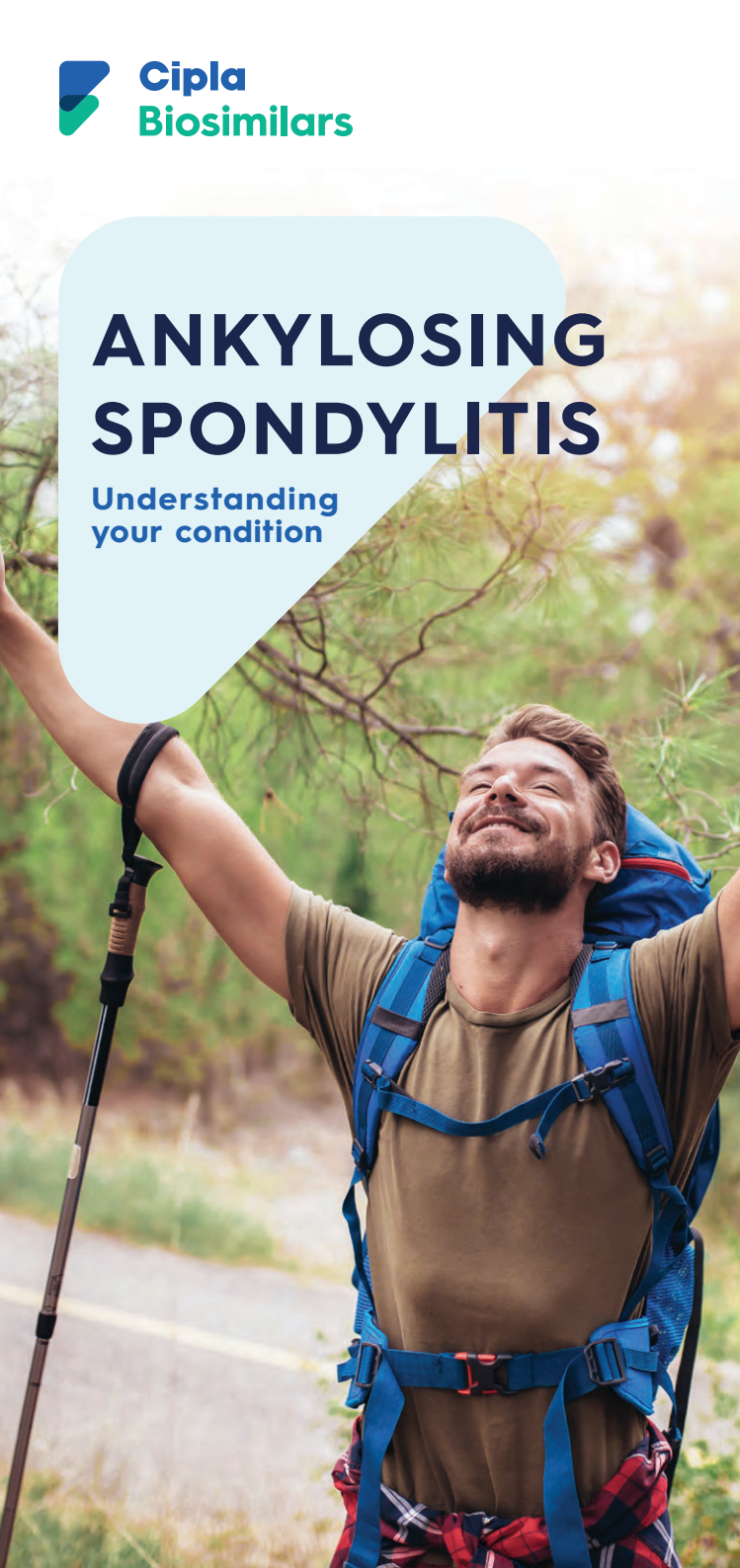
Cipla Biosimilars

ANKYLOSING SPONDYLITIS

Understanding your condition



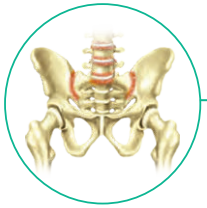
What is Ankylosing Spondylitis?

Ankylosing spondylitis (AS) is a **chronic inflamma ory disease that cause pain and stiffn ss** in the back, neck and sometimes in other joints such as the hip and heels[1].

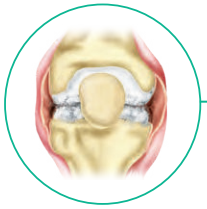
AS begins with inflammation around the bones in the spine or some joints, and later, it can sometimes cause the bones in the spine to fuse together, resulting in the loss of fl xibility and the fusion of the spine, resembling "bamboo" with an immobile position[1,2].

Spondylitis
Spinal involvement

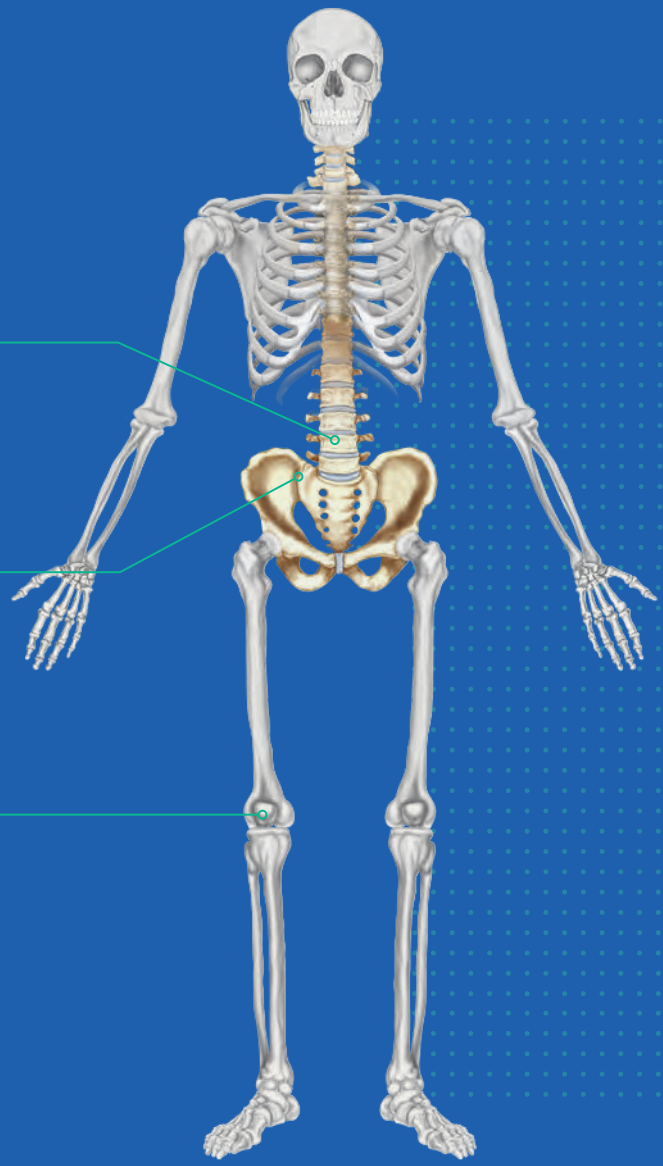
Sacroiliitis
Joint inflammatio between the sacral bone and the iliac bone



Arthritis



Arthritis of peripheral joints, which is sometimes transient, also occur in up to 50% of patients[3]



What causes Ankylosing Spondylitis?

AS is an inflamma ory disease of unknown aetiology, with a higher incidence in young males[2,3]. As an autoimmune disease, AS develops through complex interactions between genetic background and environmental factors[2].

Genetic background

AS is associated with the presence of the allele HLA-B27. In fact, 90-95% of AS patients are HLA-B27 positive[2].

Environmental risk factors

But AS does not develop in every person who is HLA-B27 positive; thus, it is clear that environmental factors are important. Even fi st-degree relatives who are HLA-B27 positive do not uniformly develop the disease[2].

Ankylosing Spondylitis

Aside from genetics, other factors are thought to be involved[4]:

Intestinal microbiome: up to 70% of patients with AS have subclinical intestinal inflammatio , suggesting that the origin of the disease may be in the gut

Infections

Mechanical stress

Changes in the immune system

Gender

What are the symptoms of Ankylosing Spondylitis?

The course of AS and its onset varies greatly from person to person, but **symptoms generally start to appear in late adolescence or early adulthood** (bewteen 17 and 45 years old)[5].

The **most common symptom** is **pain in the lower back** and buttocks. This pain usually[5]:

Comes on slowly[1,5]

Is worse in the mornings after resting and during the night[1,5]

Lasts for more than 3 months[1]

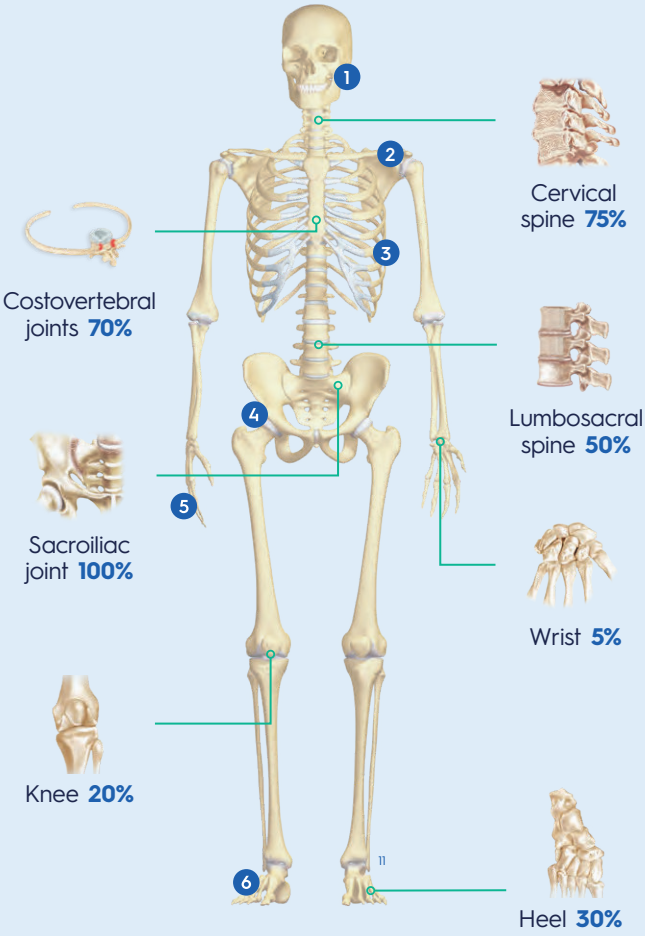
May be improved by a warm shower or light exercise[5]

Is dull and diff se rather than localised[5]

Typically becomes persistent (chronic) and is felt on both sides[5]

Which joints are affected by Ankylosing Spondylitis?

Frequency of inflammation pe region[6]



1. Jaw 15%
2. Shoulders 30%
3. Ribs 20%
4. Hip 30%
5. Fingers 5%
6. Toes 5%

Other manifestations of Ankylosing Spondylitis

Extra-articular involvement

Extraskeletal organs may also be a ected by this disease. The most common extraarticular manifestations of AS include[7]:

>50% **In ammatory bowel disease**

25% to 35% **Acute anterior uveitis**

~10% **Psoriasis**

AS is also associated with[7]:

An increased risk of **cardiovascular disease.**

Pulmonary complications as diminished chest wall expansion and decreased spinal mobility predispose patients to a restrictive pulmonary pattern.

How will my doctor diagnose my disease?

AS is diagnosed based upon the recognition of a pattern of **clinical, laboratory, and imaging finding** characteristic of the disease[8,9].

Physical examination[9]
Assessment of your fl xibility and joint tenderness.

Blood test to look at inflamma ory markers[8,9]
C-reactive protein (CRP) or erythrocyte sedimentation rate (ESR) can be assessed in patients suspected of AS.

Blood test which can identify if you carry the HL-B27 gene[9]

X-rays[9]
X-rays will show if there have been any changes to your bones and joints such as extra bone growth or fusion.

Magnetic resonance imaging (MRI) fusion[9]
MRI will show if there is any inflammation around your joints.

What are the treatment options?

Treatment depends on your symptoms and how severe your condition is[1].

The goal of treatment is[1]:

- **To relieve** your symptoms
- **To help** you do your normal activities
- **To keep** your condition from causing other problems

Non-pharmacological interventions[2,10]

- **Patient education**

- **Exercises and physical therapy**

- **Smoking cessation**

The use of a biologic agent for AS is particularly appropriate for those with high or very high disease activity, although they are e ective in patients with mild to moderate symptoms as well[10].

Pharmacological treatment[2,10]

Nonsteroidal anti-inflamma ory medications (NSAIDs)

- ✓ In many patients, NSAIDs are the only medications required as they are efficie in alleviating AS symptoms in 70-80% of patients.

Biologic therapy

- ✓ Tumour necrosis factor (TNF)-α inhibitors. TNF inhibitors are recommended for patients with an inadequate response to initial therapy with NSAIDs.
- ✓ Interleukin (IL)-17 inhibitors. In patients who have contraindications to the use of TNF inhibitors, treatment with IL-17 inhibitors is recommended.

Glucocorticoids

- ✓ Local injections of glucocorticoids into involved joint are an option for treating arthritis as they could provide immediate symptom relief.

What can I do to manage my disease?

You can reduce the chance that your conditions will cause problems if you[1]:

- **Stop smoking** (you will be less likely to have breathing problems)
- **Get plenty of calcium and vitamin D** (you will keep your bones from getting weak)
- **Do exercise** (you will prevent some of the stiffnes caused by AS)
- **Use a thin pillow** (sleeping on a thick pillow can cause neck problems in people with AS)

Benefi s of exercise[9]

- **Increased fl xibility**
  The more fl xible you are the easier it is to do everyday tasks.
- **Increased range of movement**
  The more mobility you have the easier it is to do things.
- **Improved posture**
  Better posature makes you feel better in yourself and reduces feelings of self consciousness.
- **Improved sleep**
  Exercise is physically tiring which improves sleep quality, ensuring you wake feeling refreshed.
- **Reduction in stiffn ss and pain**
  Exercise can result in less pain at night and improved sleep quality.

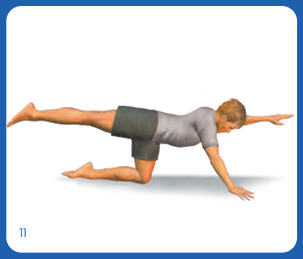
Exercises for patients with AS[9]

Repeat each of the following exercises at least fi e times:

Lie on your back with your knees bent. Tighten your stomach muscles and push your back down into the floo .

Kneel on all fours, drop your head down between your arms and slowly arch your back as high as possible.

Lengthen your neck keeping your nose parallel to the floo and hollow your back as much as possible.



In the same position, raise your right arm and your left leg. Make a straight line with your body and hold for 5 seconds. Then do the same with your left arm and right leg.

Sit upright in good posture and with both feet fla on the floo . Turn your head to the right as far as possible without letting your shoulders turn. Repeat to the left.

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11. Letter on behalf of EC Europe - 9 Feb 2022.

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